1 UNITED STATES PATENT AND TRADEMARK OFFICE

2 _____

3 BEFORE THE PATENT TRIAL AND APPEAL BOARD

4 _____

5 MERCK SHARP & DOHME LLC,

6 Petitioner,

7 v.

8 THE JOHNS HOPKINS UNIVERSITY,

9 Patent Owner.

10 _____

11 IPR2024-00240

12 Patent No. 11,591,393

13 _____

14

15 DEPOSITION OF RICHARD M. GOLDBERG, M.D.

16 Conducted Virtually

17 Friday, December 13, 2024

18 9:05 a.m. EST

19

20 Job No.: 562905

21 Pages: 1 - 207

22 Reported by: Monique Vouthouris, CCR, RPR, CRR

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6 DEPOSITION OF RICHARD M. GOLDBERG, M.D.
7 pursuant to notice, conducted virtually via Zoom
8 Videoconference, before Monique Vouthouris,
9 Certified Court Reporter, Registered Professional
10 Reporter, Certified Realtime Reporter, and Notary
11 Public in and for the States of New Jersey and New York.
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1 A P P E A R A N C E S
2 ON BEHALF OF PETITIONER, MERCK SHARP
3 & DOHME LLC:
4 DANIEL ZEILBERGER, ESQ.
5 PRESTON K. RATLIFF II, ESQ. (New York)
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13 ON BEHALF OF PATENT OWNER, THE JOHNS
14 HOPKINS UNIVERSITY, AND THE WITNESS,
15 RICHARD M. GOLDBERG, M.D.:
16 CHRISTINA D. BROWN-MARSHALL, PH.D., ESQ.
17 CASEY M. KRANING, PH.D., ESQ. (Delaware)
18 FISH & RICHARDSON, PC
19 1180 Peachtree Street NE, 21st Floor
20 Atlanta, Georgia 30309
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22

1 ALSO PRESENT:
2 KAREN M. MOREIRA, ESQ., Merck In-house Counsel
3 MARK STEWART, ESQ., Merck In-house Counsel
4 KELLI WELCH, Planet Depos Technician
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C O N T E N T S

EXAMINATION OF RICHARD M. GOLDBERG, M.D. PAGE
By Mr. Zeilberger 6
By Ms. Brown-Marshall 202

E X H I B I T S

(Exhibits attached to transcript.)

DEPOSITION EXHIBIT PAGE
Exhibit 1115 Recent Therapeutic Advances in the Treatment of Colorectal Cancer by Ciombor, et als. 98
Exhibit 1117 Trial Protocol. 120

1 P R O C E E D I N G S
2
3 RICHARD M. GOLDBERG, M.D.,
4 being first duly sworn or affirmed by the Notary,
5 testifies as follows:
6 EXAMINATION
7 BY MR. ZEILBERGER:
8 Q Good morning, Dr. Goldberg.
9 A Good morning.
10 Q My name is Daniel Zeilberger with the Paul
11 Hastings law firm. I'm appearing today for
12 petitioner Merck. I'm joined today by Preston
13 Ratliff, Isabella Cazacu, and Jinny Lim, also with
14 Paul Hastings and appearing for petitioner Merck.
15 In addition, Merck in-house counsel Karen
16 Moreira is also on the line, and Mark Stewart may
17 also join at some point today.
18 How are you feeling today, Dr. Goldberg?
19 A I'm feeling good.
20 Q Do you understand that you're testifying
21 under oath today?
22 A I do.

1 Q Is there any reason you cannot testify
2 truthfully today?
3 A No.
4 Q You retired from medical practice in 2019,
5 correct?
6 A That's correct.
7 Q And you stopped seeing patients earlier in
8 2017, correct?
9 A I saw a few patients when I was at WVU,
10 mainly covering the inpatient consult service, but I
11 didn't see patients in clinic.
12 Q In this matter you're being compensated
13 $900 per hour, as well as an additional $450 per hour
14 for travel, correct?
15 A That's correct.
16 Q Is that your standard hourly rate?
17 A It is for legal cases.
18 Q Do you have a different hourly rate for
19 non-legal cases?
20 A I do consult with companies, big pharma and
21 small start-ups, as well as technology companies, and
22 I adjust my rates downward for companies that are

1 less well-capitalized.
2 Q For those activities what is your hourly
3 rate?
4 A So for big pharma it's 6 to $700 an hour.
5 For smaller start-up companies it's $500 an hour.
6 Q And which companies do you consult for?
7 A It's about a dozen. I can look up the
8 list, if you would like a comprehensive list, but
9 I'll have to find it on my computer.
10 Q Sitting here today, which companies can you
11 recall consulting for?
12 A Taiho, Takeda, AstraZeneca, Agenus, Valor
13 Pharmaceuticals, Compass Technologies, Focal Medical.
14 Let's see. Modulation Therapeutics.
15 I'm going to just open my email because I
16 have files on the email for each of the companies
17 that I work with that will help to remind me if
18 there's anybody else that I've left off.
19 AbbVie, Artemida, Inspirna, International
20 Cellular Therapeutics, GlaxoSmithKline, GeneCentric.
21 I think that's a full list, but there may
22 be several missing. That's what I can recall.

1 Q Okay. And all of that consulting work has
2 been done after you retired?
3 A I did do some consulting before I retired,
4 but this is a recent list within the last two years.
5 Q Approximately how much time have you spent
6 working on the matter for which you are here today?
7 A I'm just going to generally recall, I would
8 guess it's more than 30 hours, but I can't be
9 precise.
10 Q Who first contacted you about this case?
11 A I was first contacted by Dung Le, who is a
12 physician at Johns Hopkins University that I've
13 collaborated with over the years, to ask if I had an
14 interest in potentially representing Johns Hopkins in
15 this matter.
16 Q And what did Mr. Dung Le tell you about
17 this case?
18 A So Dung Le is a woman. She told me that
19 Merck had patented -- or that Johns Hopkins
20 University had patented some indications related to
21 the use of pembrolizumab in microsatellite
22 instability and had a dispute with Merck about the

1 validity of that patent and required someone such as
2 me who had experience with pembrolizumab,
3 participated in the initial clinical trial
4 KEYNOTE-017. And I was knowledgeable about the
5 management of gastrointestinal cancer patients, in
6 particular colorectal cancer patients, both before,
7 during and after the initial studies with
8 pembrolizumab in that setting.
9 Q Did Dung Le tell you what you would be
10 testifying about in this proceeding?
11 A No. She just asked me if I was interested,
12 and then said she would have somebody from the Fish
13 law firm contact me to give me further details.
14 Q And so did you tell Dung Le that you were
15 interested in working on this case?
16 A I told her I was interested in speaking
17 with the legal team to find out more details about
18 what the case entailed.
19 Q So after speaking with Dung Le, was the
20 next person you spoke to an attorney from Fish &
21 Richardson?
22 A I believe it was, yes.

1 Q When were you retained for this case?
2 A It was sometime early this year. I don't
3 recall exactly when. I could check my records if
4 it's important.
5 Q Do you recall when you started working on
6 this case?
7 A Give me a minute and I'll look in my email
8 files so that I can be more precise.
9 So the first record I have of a contact
10 with a Fish lawyer is with Todd Miller and it
11 occurred on February 8th, 2024.
12 Q And what did Todd Miller tell you about
13 this case?
14 MS. BROWN-MARSHALL: Objection, counsel.
15 I'm going to object to the extent that this calls for
16 attorney-client privileged information.
17 And I would caution the witness not to
18 disclose any conversations with counsel, the content
19 of any conversations with counsel.
20 Q Dr. Goldberg, were you already retained by
21 JHU on February 8th, 2024?
22 A Let me just look and see.

1 So I have a letter dated February 13th,
2 2024 from Christina Brown-Marshall, who is on this
3 call, stating, "In follow-up of our recent
4 conversations, this letter confirms that you have
5 agreed to act as an independent consultant assisting
6 Fish & Richardson, counsel for Johns Hopkins
7 University, in connection with the litigation styled
8 Merck Sharp & Dohme LLC versus John Hopkins
9 University, Case 1:22-cv-03059-JRR. This letter
10 contains the terms of our agreement."
11 Q So on February 8th, 2024 in the
12 communication you received from Todd Miller, what did
13 you -- what information did you receive?
14 A Well, that's a long time ago, but my memory
15 is that he gave me a thumbnail sketch of the issues
16 in the lawsuit, and asked me about my experience
17 relevant to the development of pembrolizumab for the
18 indication of treatment of MSI-high cancers and
19 MSI-high colorectal cancers in particular. And we
20 agreed that I had the relevant experience that he
21 felt was needed to represent the interests of Johns
22 Hopkins University in this case.

1 Q And so what you just communicated to me,
2 that was all contained in this email you referred to
3 from February 8th?
4 A No. We had a telephone discussion about
5 this, and as a consequence of that telephone
6 discussion, a letter was generated by
7 Ms. Brown-Marshall that detailed the agreement that
8 we were going to work under.
9 Q So what was said to you in the February 8th
10 email that you referred to?
11 A Let me go back to that email.
12 So we decided to -- that we could work
13 together. I did disclose to Mr. Miller that I was
14 consulting with Merck as a member of the data safety
15 monitoring boards of several phase III studies that
16 were being conducted by Merck, and that that would
17 represent a potential conflict of interest for me,
18 and that I was prepared to resign from those data
19 safety monitoring boards, which I subsequently did.
20 Q So what did you see your assignment in this
21 case as?
22 A I believe that my assignment was to

1 particularly provide the background and testimony
2 related to the fact that the use of pembrolizumab met
3 an unmet need in the management of patients with
4 colorectal cancer in particular.
5 I've also been asked to prepare some
6 information regarding the non-colorectal indications
7 for pembrolizumab that, as I understand it, that is
8 not relevant to today's discussion.
9 Q Before working on the present matter, have
10 you ever worked with the Fish & Richardson law firm?
11 A I have not.
12 Q Okay. I know you have a computer in front
13 of you today. Do you have anything else with you
14 today?
15 A I do. I have a copy of my declaration
16 that's clean, I have a bottle of water, and some
17 Kleenex.
18 Q And on your computer, just so I understand
19 what sort of setup you have, what do you have on your
20 screen?
21 A I have this Zoom call and a toolbar.
22 Q Do you have any of the files or exhibits

1 relating to this proceeding on your computer?
2 A They're on my computer, but they're not
3 open or on my screen.
4 Q And you said you have a clean copy of your
5 declaration printed out. Do you have any of the
6 exhibits that are cited in your declaration in hard
7 copy form?
8 A I don't have them, but I believe that Casey
9 has some of them. They're not visible to me.
10 Q Okay. And who is in the room with you
11 today?
12 A Casey.
13 Q Anyone else?
14 A Just the two of us.
15 Q And I know you said your declaration is a
16 clean copy, but are there any Post-it notes or tabs
17 or anything like that on your declaration?
18 A No.
19 Q How much time did you spend preparing for
20 today's deposition?
21 A Well, I would consider all the time that
22 I've spent working with Fish to be in preparation for

1 today's deposition. So I'm going to guess that over
2 time it was more than 30 hours prior to this week and
3 then probably another 15 hours this week.
4 Q And was that most recent 15-hour
5 preparation time by yourself or with other people?
6 A Most of it was by myself, but some of it
7 was with Casey or with Chrissy.
8 Q Other than Casey and Chrissy, did you speak
9 with anyone else in the most recent time, the 15
10 hours of preparation for your deposition?
11 A I did not.
12 Q The declaration that you have in front of
13 you today, on the cover page is it marked JHU 2090 on
14 the bottom right?
15 A It is.
16 Q And the cover page is signed on October
17 4th, 2024, correct?
18 A By me, yes.
19 Q And that's your signature on the cover
20 page?
21 A It is.
22 Q Did you read your declaration carefully

1 before you signed it?
2 A Well, I wrote the declaration, and, yes, I
3 did read it carefully before I signed it and I've
4 read it many times since.
5 Q Okay. And you say you wrote your
6 declaration. You wrote it by yourself?
7 A I wrote the initial draft by myself. Then
8 I sent it off to the Fish attorneys, who read it
9 over, and we revised some of the language in the
10 report based on our conversations.
11 Q Were there any substantive changes between
12 this initial draft you wrote by yourself and the
13 version that was eventually signed on October 4th,
14 2024?
15 A So some of the language in this is legal
16 language that, generally, when I am quoting that
17 language, I say I understand from my discussions with
18 the lawyers that. And so I'm not a lawyer, I'm a
19 physician and researcher, and so I required some
20 teaching from the lawyers about what was proper to
21 put in the deposition regarding the legal tenets of
22 the dispute.

1 Q Did you make any changes relating to the
2 science that you discuss in your declaration between
3 the initial draft and the version that was signed on
4 October 4th, 2024?
5 MS. BROWN-MARSHALL: Objection; vague.
6 A So I don't remember specific changes, but,
7 you know, it was a work in progress, and each time I
8 read it I made some changes. So it was a work in
9 evolution before it was finalized and signed.
10 Q For the eventual version of your
11 declaration that was signed, did you understand every
12 statement, opinion, and conclusion that's contained
13 in your declaration?
14 A I believe so. You know, some of the legal
15 language is a bit arcane, and sometimes I need to be
16 reminded of the specific meanings of some of the
17 legal phrases. And if that is relevant today, I'll
18 tell you what the issues are.
19 Q But sitting here today, are you aware of
20 any statements, opinions, or conclusions contained in
21 your declaration that you do not understand?
22 A I believe I understand it.

1 Q And you are familiar with the content of
2 the documents that you reference in your declaration.
3 Is that right?
4 A Yes.
5 Q Are there any errors in your signed
6 declaration?
7 A There are a few places where I noticed
8 there was a missing word, something like a "which" or
9 a "to" or an "a," but that didn't change the meaning
10 of the sentences.
11 Q Do you have any corrections to your signed
12 declaration that you wish to make today?
13 A I didn't catalog the places where there was
14 a missing word. I can, if that's necessary, and
15 supply that information to you, or we can point it
16 out as we go through the report. None of it changes
17 the meaning of the sentences.
18 Q The declaration you have in front of you
19 relates to U.S. Patent No. 11,591,393, correct?
20 A Correct. I believe it's referenced as the
21 '393 patent throughout my report.
22 Q Okay. And if I refer to it today at any

1 point as the '393 patent, you'll understand what I'm
2 talking about?
3 A I will.
4 Q Did you review the '393 patent?
5 A I have.
6 Q Do you understand the '393 patent?
7 A I believe so.
8 Q What experience do you have that enables
9 you to understand the '393 patent?
10 MS. BROWN-MARSHALL: Objection; vague.
11 A So, you know, I could start with my
12 experience as a GI medical oncologist, my experience
13 as an expert witness in other cases. I'm not sure
14 exactly what you're asking me. Do you want a
15 two-minute response or a 20-minute response?
16 Q I just want to understand what experience
17 you think makes you qualified to understand and opine
18 on the '393 patent.
19 A So have you read my report?
20 Q I have.
21 A Okay. So the first -- first 15 pages
22 discuss my qualifications as a GI medical oncologist,

1 a clinical trialist, a medical researcher, a medical
2 teacher, an author of multiple publications, an
3 editor for multiple medical journals, and my
4 experience caring for thousands of patients,
5 including thousands of patients with colorectal
6 cancer.
7 So I believe -- and I would also add my
8 interest in and experience working with genetic
9 predisposing syndrome, such as Lynch syndrome,
10 related to colorectal cancer.
11 I also have served as an expert witness in
12 two other patent disputes. One was a patent dispute
13 where I represented Genentech against Amgen, who had
14 a generic version of bevacizumab known as MVASI, and
15 that case was settled after deposition, but outside
16 of court.
17 And then I represented Taiho in a dispute
18 with five generic drug companies that I believed that
19 the patent that they had for LONSURF, which is a
20 combination drug used to treat colorectal cancer, was
21 obvious and invalid, and Judge Connolly in Delaware
22 ruled in favor of Taiho in that dispute.

1 So those are my two patent law testimony
2 experiences.
3 I've also been a witness in several
4 malpractice suits where I've represented the
5 physician, but none of those are recent.
6 Q In preparing your declaration, did you have
7 any conversations with any JHU employees or
8 scientists?
9 A I did.
10 Q Who?
11 A So I had conversations with Dung Le, who is
12 the first author of the New England Journal of
13 Medicine paper on the KEYNOTE study and who I worked
14 with closely as we were enrolling patients in that
15 study.
16 I also had some conversations with Luis
17 Diaz, who is also a member of the Hopkins team, who
18 was the individual who first had the insight that the
19 one of 33 patients who responded to nivolumab in the
20 Topalian study might have microsatellite instability.
21 I also spoke with several of the other
22 expert witnesses retained by Johns Hopkins in

1 preparation of their reports.
2 Q What did you speak to Dung Le about in your
3 conversations with her?
4 A Well, the main purpose of my conversation
5 with her was to get an update on the study. There
6 have been two manuscript publications, one in the New
7 England Journal of Medicine and another in Science,
8 both of which were interim reports. I was interested
9 to know what the five-year survival data was for
10 patients who had been enrolled in the study, and that
11 is not information that is in the public domain,
12 although, as I understand it, that information has
13 been submitted for consideration for an upcoming ASCO
14 meeting. It is not yet published.
15 Q Why were you interested in knowing the
16 five-year survival data?
17 A Because so many -- so I ended up treating,
18 I believe, four patients on the study. Two of them
19 had very advanced disease. Both of them are
20 disease-free. It's now close to 10 years from the
21 time that they initiated treatment. And that
22 suggested to me that there was a high rate of

1 long-term survival among these patients. And so it
2 was of great interest to me, as it is to the medical
3 community, to know what the median overall survival
4 was for the three categories of patients treated on
5 the three-arm study.
6 Q Do you discuss the five-year survival data
7 in your declaration?
8 A I do.
9 Q And you said that the main purpose of your
10 conversation with Dung Le was what you just said. Is
11 there anything else you discussed with Dung Le?
12 A I don't remember all of the details, but
13 that was the main point of the discussion. I did
14 also read her -- her declaration.
15 Q Do you remember any of the other details?
16 A I think we exchanged some pleasantries and
17 we talked about plans to present at future scientific
18 meetings.
19 Q Why did you speak with Luis Diaz?
20 A Well, Luis Diaz and I have been friends and
21 coworkers for many years and we see each other
22 frequently at meetings.

1 You know, this finding was one that in many
2 ways revolutionized our thinking about the treatment
3 of MSI-high cancers and is a great success that we
4 both participated in and so it's a common reason for
5 celebration when we get together.
6 Q But you said you spoke to Luis Diaz to
7 prepare your declaration. Why did you see fit to do
8 that?
9 A Maybe I should correct that and say I spoke
10 with Luis Diaz while I was preparing my declaration,
11 but I didn't have a specific question for him and he
12 didn't provide me with any additional information
13 that wasn't already known to me.
14 Q Did you reach out to him?
15 A Well, we see each other at meetings, you
16 know, we say hi to each other and shake hands and
17 talk about the good times.
18 Q Got it. So you saw him at a meeting and
19 that led to talking about how you're preparing a
20 declaration in this proceeding?
21 A Correct.
22 MS. BROWN-MARSHALL: Objection;

1 mischaracterizes previous testimony.
2 Q You said you spoke to other experts. Which
3 other experts?
4 A So I spoke with Nils -- is it Lundgren? --
5 who is the former employer of Merck Sharp & Dohme,
6 who is an expert witness on the background of the
7 development of PD-1 inhibitors. And then I also
8 spoke with an economics expert, but I don't remember
9 that person's name.
10 Q What did you speak about with Nils
11 Lundgren?
12 A I spoke about his experience with the
13 development of PD-1 inhibitors while he was employed
14 at Merck and/or -- I'm sorry, at BMS. And we also
15 talked about the mechanism of action of PD-1
16 inhibitors, their engagement with T cells, and how
17 the biology is understood at this time. And we
18 talked about the novelty of the findings that came
19 out of the treatment of MSI-high patients.
20 And he is not a clinician, so I provided
21 him with my clinical experience with the drugs. He
22 provided me with his laboratory and scientific

1 perspectives on the development of PD-1 inhibitors.
2 Q And just to be clear, I think you said
3 "Nils Lundgren." Do you mean Dr. Nils Lonberg?
4 A Right. Sorry, I couldn't remember the
5 details of his last name.
6 Q Did you rely on the information that
7 Dr. Lonberg provided to you in preparing your
8 declaration?
9 A I don't remember the exact timing of my
10 discussion with him, but my memory is that our
11 discussion occurred after I had signed my report.
12 Q What about your discussion with the
13 economic expert that you referred to, was that before
14 or after you prepared your report?
15 A Again, it was around the same time, and I
16 believe it was after I had prepared my report. I
17 don't make any reference to the economic issues in my
18 report.
19 Q Why did you speak to the economic expert?
20 A Well, I had interest in the economics of
21 pembrolizumab and that person was expert in that, and
22 it was one of the indicia that I think supports the

1 patent in that there was commercial success with the
2 agent and I was interested in learning about that.
3 Q You don't discuss any commercial or alleged
4 commercial success in your declaration, though,
5 correct?
6 A I don't believe so. If I do, it's just in
7 passing. It wasn't the point of my testimony.
8 Q Did you provide any opinions or information
9 to either Dr. Lonberg or this economic expert that
10 you're referring to?
11 A I don't believe that I did.
12 Q Other than the people you've already
13 identified and any attorneys at the Fish & Richardson
14 law firm, did you speak with anybody else as part of
15 this proceeding?
16 A I did not.
17 Q If you could please open your declaration
18 to paragraph 55.
19 A Okay. I've opened it. Do you want me to
20 read the paragraph or are you going to point out --
21 Q No. So in the first sentence of paragraph
22 55 you say that you understand from conversations

1 with the JHU scientists that when they tried to
2 interest the research teams at either BMS or Merck in
3 funding the trial to test their hypothesis, neither
4 companies' teams were interested, correct?
5 A I see that statement.
6 Q When you referred to JHU scientists in
7 paragraph 55, who were you referring to?
8 A I'm referring to Dr. Le and to Dr. Diaz.
9 Q So this is information that both Dr. Le and
10 Dr. Diaz informed you of?
11 A Well, I also have some other sources for
12 the statement, which I can tell you about, if you
13 would like.
14 Q Well, in your declaration you don't cite
15 any other sources, correct?
16 A Not here, that's correct. I do cite the
17 cancer letter at the bottom of the page 35 is the
18 reference there, and the sentence that the 35
19 indicates is, I'll read it to you, "because they were
20 unable to obtain pharmaceutical company funding, they
21 funded it with JHU resources and obtained additional
22 support through a grant from the charitable

1 organization Swim Across America."
2 If you read the New England Journal of
3 Medicine paper, it cites several other charities that
4 provided some resources for the study. But I believe
5 the largest amount of support came from Swim Across
6 America.
7 Q And when you say that the JHU scientists
8 tried to interest the research teams at BMS and
9 Merck, what did the JHU scientists do to try to
10 interest those research teams?
11 A You would have to ask them that question.
12 Q You don't know what they did to try to
13 interest the research teams at BMS and Merck,
14 correct?
15 A I can speculate on it if you would like me
16 to, but they didn't specifically tell me what their
17 arguments were.
18 Q Shifting gears, you have been affiliated
19 with groups that develop, run and analyze trials to
20 advance cancer treatment and the understanding of
21 cancer biology, correct?
22 A Correct.

1 MS. BROWN-MARSHALL: Objection; vague.
2 A So I've worked with National Cancer
3 Institute funded cooperative groups, oncology
4 cooperative groups that sponsor clinical research and
5 translational research in cancer patients.
6 My specific area of interest is
7 gastrointestinal cancer, subset specific area of
8 interest is colorectal cancer.
9 I've also been involved in the
10 administration of those groups. I've run the GI
11 committee for a now defunct group called the North
12 Central Cancer Treatment Group. That group merged
13 into what is now called The Alliance.
14 I also worked prior to the merger with the
15 Cancer and Acute Leukemia Group B, known as CALGB,
16 and I chaired the GI committee for that.
17 Once The Alliance was formed from the
18 merger of those two groups plus The American College
19 of Surgeons Oncology Group, I became the associate
20 group chair for The Alliance where my
21 responsibilities went beyond just GI cancer to the
22 administration of the entire group. I also serve on

1 the board of directors of that group and on the board
2 of directors of the Alliance Foundation.
3 Q How many trials have you personally
4 developed to advance cancer treatment and the
5 understanding of cancer biology?
6 MS. BROWN-MARSHALL: Objection; vague,
7 compound.
8 A So I can't give you a precise number. But
9 I can tell you that personally I've been the
10 principal investigator on dozens of trials.
11 In my role as the GI committee chairs for
12 NCCTG and CALGB, I administered a portfolio of
13 studies and was responsible for the development of
14 probably over a hundred protocols, but that's just a
15 guess. I then investigated issues in GI cancers that
16 include anywhere in the GI tract from the esophagus
17 to the anus.
18 I also participated in early phase studies
19 in that we had a phase 1 program when I worked at
20 Mayo Clinic, when I worked at University of North
21 Carolina, and when I worked at Ohio State where we
22 were doing first-in-man studies of new agents or

1 first-in-man studies of combinations of agents that
2 had been previously approved but not tested together.
3 So I have a long experience in clinical
4 trials that ran just from phase 1 two to three
5 clinical trials and I describe those trials in my
6 declaration.
7 Q So it's fair to say, Dr. Goldberg, that
8 over the course of your career, you've been involved
9 in and analyzed many cancer-related clinical trials?
10 A I have. You know, I have over 400
11 peer-reviewed publications. I also work with
12 international groups that do Gould analyses of
13 clinical trials from across the world, and I have
14 publications with many of the leading clinical
15 trialists in GI oncology.
16 Q In addition to drafting your own
17 publications relating to clinical trials, I assume
18 you also have reviewed many publications relating to
19 clinical trials over your career. Is that fair?
20 A Well, I've reviewed every one of the 400
21 publications that I'm a co-author on. I also have
22 been a reviewer for many prestigious medical

1 journals, including the New England Journal of
2 Medicine, The Lancet, the Annals of Oncology, the
3 Journal of Clinical Oncology, JAMA, JAMA Oncology.
4 In addition, I serve as the executive
5 editor and previously the GI oncology editor for the
6 online medical textbook known as UpToDate where we
7 evaluate the outcomes of studies and relate them to
8 the entire body of knowledge that clinicians would
9 use to manage patients. And this UpToDate textbook
10 is the go-to reference for I would say the majority
11 of physicians in the U.S. and is available
12 internationally as well.
13 Q You believe you played a role in getting
14 pembrolizumab approved for its MSI-high colorectal
15 cancer indication, correct?
16 MS. BROWN-MARSHALL: Objection; vague.
17 A Yes.
18 Q I couldn't hear you over the objection,
19 Dr. Goldberg. Can you please repeat your answer?
20 A Yes, I think I played multiple roles.
21 MR. ZEILBERGER: And I'll just note,
22 counsel, you've done it many times now, making

1 speaking objections that are improper at the PTAB.
2 I'll ask you to refrain from doing so over the course
3 of the remainder of the deposition.
4 MS. BROWN-MARSHALL: Counsel, I made a
5 short two-word objection.
6 MR. ZEILBERGER: You made an objection that
7 is specifically listed as an improper objection in
8 the Patent Trial Practice Guide.
9 MS. BROWN-MARSHALL: Counsel, we'll
10 continue.
11 MR. ZEILBERGER: Are you confirming that
12 you'll refrain from improper objections, counsel?
13 MS. BROWN-MARSHALL: No. I said, counsel,
14 we'll continue the deposition.
15 MR. ZEILBERGER: Okay. I am noting for the
16 record that the Patent Trial Practice Guide at page
17 128 specifically says examples of objections that
18 would not be proper are "objection; vague."
19 BY MR. ZEILBERGER:
20 Q Dr. Goldberg, if you could please turn to
21 paragraph 66 of your declaration.
22 A I have that in front of me.

1 Q In paragraph 66 you indicate that you
2 prescribed pembrolizumab to your MSI-high colorectal
3 cancer patients until you stopped seeing patients in
4 2017, correct?
5 A Right.
6 Q So you prescribed pembrolizumab for two
7 years, correct?
8 A Well, I prescribed pembrolizumab as part of
9 the clinical trial starting in 2013, so my experience
10 with it really is at least four years.
11 Q Outside of the context of the clinical
12 trial, you prescribed pembrolizumab for two years,
13 correct?
14 A Well, the FDA approval I believe was in
15 2017, and so I only had an opportunity to prescribe
16 it after it was FDA approved.
17 Q Pembrolizumab is a PD-1 inhibitor, correct?
18 A Correct.
19 Q Is pembrolizumab the only PD-1 inhibitor
20 that you prescribed to MSI-high colorectal cancer
21 patients?
22 A Yes.

1 Q Are you aware that there are other PD-1
2 inhibitors that are approved for MSI-high colorectal
3 cancer?
4 A I'm aware that there are other PD-1
5 inhibitors that are approved for MSI colorectal
6 cancer, but they were not approved prior to 2017 when
7 I ceased practicing.
8 Q Got it. So those other PD-1 inhibitors
9 were not options during the time period when you were
10 prescribing PD-1 inhibitors?
11 A Well, nivolumab was on the market, but it
12 did not have this indication, so I wouldn't have
13 prescribed it.
14 Q Moving forward to paragraph 72 of your
15 declaration.
16 A I have it in front of me.
17 Q Thank you. You indicate in paragraph 72
18 that at Ohio State University you rapidly adopted
19 universal MSI testing for your patients and used PD-1
20 inhibitors when appropriate, correct?
21 A I see that.
22 Q Which PD-1 inhibitors are you referring to

1 in paragraph 72?
2 A Well, I left Ohio State at the end of 2017.
3 I was using pembrolizumab in the GI oncology clinic,
4 as were the other GI medical oncologists that I
5 worked with.
6 Ohio State University has a full service
7 cancer hospital and so we were also treating patients
8 with lung cancer and melanoma and bladder cancer. I
9 was the physician in chief of the cancer hospital.
10 So individuals who reported to me were using
11 nivolumab for the approved indications in their
12 disease sites. But in the GI oncology group we were
13 exclusively using pembrolizumab, to my knowledge, at
14 that time.
15 Q And when you say "when appropriate" in
16 paragraph 72, what are you referring to?
17 A According to the FDA-approved indications,
18 or if a patient was eligible for a clinical trial
19 that included a PD-1 inhibitor, it would be
20 appropriate to administer it as part of the clinical
21 trial.
22 Q Are there any instances when a patient

1 would fall under the FDA-approved indications but it
2 would not be appropriate to give them a PD-1
3 inhibitor?
4 MS. BROWN-MARSHALL: Objection to the form
5 of the question.
6 A So if you read the package insert for PD-1
7 inhibitors, including for pembrolizumab, it does have
8 a number of cautions such as the use of PD-1
9 inhibitors in individuals with autoimmune disease,
10 which can be exacerbated by administration of PD-1
11 inhibitors.
12 So the short answer to your question is
13 yes, there are contraindications to the use of PD-1
14 inhibitors.
15 Q You alluded to it earlier today, you are
16 familiar with the clinical trial study of
17 pembrolizumab in patients with microsatellite
18 unstable tumors that first publish as a study record
19 on June 10th, 2013, correct?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A So can you tell me which KEYNOTE study that

1 is?
2 Q Sure. I can direct you to page 11 of your
3 declaration, footnote 2.
4 A Restate your question.
5 Q You are familiar with the study of
6 pembrolizumab in patients with microsatellite
7 unstable tumors that first published as a study
8 record on June 10th, 2013, correct?
9 A Correct.
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 Q If I refer to this study as the 2013
13 MSI-high study, will you understand what I'm
14 referring to?
15 A Yes.
16 Q You participated in the 2013 MSI-high
17 study, correct?
18 MS. BROWN-MARSHALL: Objection; form.
19 A I enrolled patients on this study and I was
20 the principal investigator at Ohio State for this
21 study.
22 Q How did you first learn of the 2013

1 MSI-high study?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A So I learned about the study when Bert
5 Vogelstein, who worked at Johns Hopkins University
6 and led the lab that has made the seminal discoveries
7 about the biology of colorectal cancer, contacted my
8 friend and colleague Dr. Albert de la Chapelle.
9 Dr. de la Chapelle was a molecular geneticist who
10 worked at Ohio State University and helped to
11 elucidate the mechanism behind microsatellite
12 instability, both as it applies to patients with
13 Lynch syndrome, who inherit it, and as it applies to
14 patients who have hypermethylation of their DNA and
15 therefore have microsatellite instability that's
16 acquired and not inherited.
17 Dr. Vogelstein and Dr. de la Chapelle were
18 close colleagues, and Dr. Vogelstein contacted Albert
19 to see if there might be an interest in participating
20 in this clinical trial from the GI team at Ohio
21 State.
22 Q What made Ohio State want to participate in

1 the 2013 MSI-high study?
2 MS. BROWN-MARSHALL: Objection to the form
3 of the question.
4 A So I would say that there were multiple
5 reasons. One was the long-standing collaboration
6 between Dr. Vogelstein and Dr. de la Chapelle.
7 Two was we had a very strong clinical
8 genetics program at Ohio State and had multiple
9 publications in prestigious journals, like the New
10 England Journal of Medicine, about screening patients
11 for Lynch syndrome, and so we had expertise in the
12 molecular genetics that would be required to be a
13 full participant in the study.
14 We also -- the James Cancer Hospital, of
15 which I was physician in chief, is the third largest
16 cancer hospital in the country. So not only does it
17 have a large volume of patients with inherited cancer
18 predisposition syndromes, such as Lynch syndrome, it
19 has a large volume of patients in general, and
20 there's always a desire for clinical trials such as
21 this to come to a rapid answer.
22 I believe that from the Hopkins

1 perspective, they wanted to harness the engine that
2 we could provide for patient accrual. We, of course,
3 were very interested in working with Dr. Vogelstein,
4 he's one of the most impactful and highly published
5 researchers in medicine and has made seminal
6 discovery in the molecular underpinnings of
7 colorectal cancer, and I think any oncologist and
8 researcher would consider it a privilege to work with
9 his team.
10 So there were many reasons for us to want
11 to participate in the study.
12 Q As part of your answer you said there was a
13 desire to come to a rapid answer. What do you mean
14 by that?
15 A Well, when a hypothesis is generated,
16 there's an interest in finding out if the hypothesis
17 is true or not. And there are many trials that are
18 created that never fully accrue and, therefore, are
19 unable to answer the question that they were designed
20 to interrogate.
21 And so it's common for large cancer
22 centers, such as Ohio State and Johns Hopkins and

1 others, to enter into consortia agreements so that
2 their accrual engines can be harnessed to answer
3 questions as rapidly as possible.
4 Q For this particular study, why was there a
5 desire to come to a rapid answer?
6 MS. BROWN-MARSHALL: Objection to the form
7 of the question.
8 A So I don't think it was peculiar to this
9 study. I think we want to answer questions quickly
10 so that we can garner the value of the question that
11 we answered and either move it forward or discard it
12 if it turns out that the hypothesis was not
13 confirmed.
14 You know, we feel great pressure to cure
15 cancer patients. And until we can cure every cancer
16 patient, there are unmet needs that researchers, such
17 as myself, feel pressured to try and resolve. So we
18 were trying to do the best we could to both
19 understand the disease and to bring our
20 understandings to the clinic to help our patients.
21 Q When you were working at Ohio State, was
22 Ohio State proposed with a small number of clinical

1 trials or a large number?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A Well, I can't tell you exactly how many
5 clinical trials we had. But, you know, we had a
6 3,000-bed -- or 300-bed cancer hospital that was full
7 every day. We had hundreds of physicians seeing
8 cancer patients. We had a very large clinical trials
9 office and participated in many NCI and
10 pharmaceutical sponsored as well as investigator
11 initiated clinical trials. You know, that was our
12 reason for being.
13 Q Got it. So are you saying that Ohio State
14 was willing to participate in most clinical trials
15 that were proposed to them?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A Well, we're always interested in having
19 clinical trials to offer to our patients because
20 often they provide either cutting edge new trials
21 that are new -- access to new drugs that patients
22 clamor for, and we wanted to advance cancer

1 treatment.
2 You know, if we didn't think a study was a
3 good study, we would evaluate it and not approve it.
4 But we were receptive to opportunities to expand the
5 repertoire of things that were available to our
6 patients when we considered them to be proper and
7 meaningful.
8 Q Were most clinical trials accepted or
9 rejected at Ohio State?
10 A Well, I don't have a statistic on that.
11 But I think that we would accept more clinicals
12 trials than we would reject. It would take something
13 specific to reject a trial.
14 For example, if I had a first line
15 metastatic colorectal cancer trial and somebody
16 approached with me another first line colorectal
17 cancer trial that completely overlapped in terms of
18 eligibility, we would say we already have a study for
19 that, and therefore we're not interested in another
20 study that would compete with the study we've already
21 committed to. Or if we said, okay, well, we don't
22 see this rare type of tumor, and therefore we can't

1 spend the resources to open the trial and keep it
2 running because we're unlikely to be able to
3 contribute much to the -- to satisfy the accrual
4 goals of this study.
5 So it's a complicated series of
6 considerations that balances institutional resources
7 with institutional and investigator interests and
8 patient interests.
9 MS. BROWN-MARSHALL: Counsel, we have been
10 going for over an hour now. Is now a good time to
11 take a break?
12 Q Dr. Goldberg, would you like a break?
13 A I would.
14 MR. ZEILBERGER: Sure, we can take a break.
15 (Recess 10:10 a.m. - 10:15 a.m.)
16 BY MR. ZEILBERGER:
17 Q Dr. Goldberg, you were not involved when
18 the 2013 MSI-high study was being developed between
19 Merck and JHU in 2012, correct?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A The protocol had been finalized when we

1 were asked to join.
2 Q And just to be sure, you, yourself, had no
3 involvement in the 2013 MSI-high study before the
4 protocol was finalized, correct?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A That's correct.
8 Q Do you have any personal knowledge about
9 whether Merck and JHU discussed funding of the 2013
10 MSI-high study while negotiating the contract
11 covering it?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A I was not involved in those discussions. I
15 have knowledge from what I was told by Drs. Le and
16 Diaz. And then I also read I believe it was a Forbes
17 article that described the negotiation between Merck
18 and JHU. So those are my sources of information
19 about this.
20 Q And when you refer to a Forbes article, are
21 you talking about the Forbes article that you cite in
22 your declaration?

1 A Yes.
2 Q And did you assume that that Forbes article
3 was accurate for your declaration?
4 A I did.
5 Q Merck provided pembrolizumab throughout the
6 2013 MSI-high study, correct?
7 MS. BROWN-MARSHALL: Object to the form of
8 the question.
9 A They had to because there was no other way
10 to obtain pembrolizumab than to get it through Merck.
11 Q Do you know what the value of pembrolizumab
12 provided by Merck throughout the 2013 MSI-high study
13 would amount to?
14 MS. BROWN-MARSHALL: Object to the form of
15 the question.
16 A I have no idea.
17 Q So when you prescribed pembrolizumab to
18 your patients, you had no idea what it cost?
19 MS. BROWN-MARSHALL: Object to the form of
20 the question.
21 A So I'm an academic medical oncologist, and
22 I had no role in purchasing or charging for the drugs

1 that I prescribed. I just wrote the order according
2 to the indications.
3 Q During the course of the 2013 MSI-high
4 study, were there any amendments to the study
5 protocol?
6 MS. BROWN-MARSHALL: Objection to the form
7 of the question.
8 A I don't recall, but there almost always are
9 amendments to study protocols.
10 Q Were you involved in any discussions
11 relating to any amendments to the 2013 MSI-high study
12 protocol?
13 MS. BROWN-MARSHALL: Objection to the form
14 of the question.
15 A Not that I recall.
16 Q You don't have any personal knowledge about
17 who drafted the 2013 MSI-high study protocol,
18 correct?
19 A That's not true. The Hopkins team drafted
20 it is my understanding.
21 Q I see. So you were involved when the
22 MSI-high study protocol, the 2013 MSI-high study

1 protocol was drafted?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A So I'm not sure I understand your question.
5 Are you asking me if I know who drafted the protocol
6 or if I was involved in drafting the protocol?
7 Q I'm asking if you personally know from your
8 own knowledge who contributed to the drafting of the
9 2013 MSI-high study protocol.
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A I believe that's stated in the New England
13 Journal of Medicine publication by Le.
14 Q So the basis of your understanding is what
15 Dr. Le told you?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A So it's based on what Dr. Le told me and
19 what Dr. Le and we told the world when we published
20 the paper.
21 Q Can you clarify what you mean when you say
22 that the basis of your understanding is what "we told

1 the world when we published the paper"?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A Do you have a copy of the paper?
5 Q I'm trying to understand, Dr. Goldberg,
6 what the basis is for your understanding about who
7 contributed to the drafting of the 2013 MSI-high
8 study protocol.
9 A And I was trying to bring up a copy of the
10 manuscript so that you could read what I read in it.
11 Q So you relied on what you read in the New
12 England Journal of Medicine article of which you're a
13 co-author. Is that right?
14 A In part.
15 Q What else did you rely on?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A So as I've stated, I had discussions with
19 the Hopkins team about how the protocol came to be,
20 and I also read the Forbes article in preparing this
21 declaration.
22 Q During your involvement in the 2013

1 MSI-high study, did you communicate with anyone at
2 Merck regarding the study?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A I did not.
6 Q How did you obtain the pembrolizumab used
7 for treatment in the 2013 MSI-high study?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So the procedure for opening a clinical
11 trial at Ohio State and other places is that an
12 investigator is engaged by an external party, whether
13 that's Johns Hopkins University or a pharmaceutical
14 company. We discuss the trial with our study teams.
15 If we decide that we're going to engage in the study,
16 then it's presented to the Clinical Trials Office.
17 The Clinicals Trial Office then goes
18 through the activation process, which includes
19 submitting the clinical trial to the IRB. Once the
20 study is opened, the clinical trials pharmacy has
21 policies and procedures for obtaining the drug, and
22 that is done under my supervision but without my

1 direct knowledge for a study in which I'm the
2 principal investigator at our institution.
3 Q Were you involved in selecting patients for
4 the 2013 MSI-high study?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A I enrolled patients in the study.
8 Q How did you determine which patients to
9 enroll?
10 A By reading the study eligibility criteria
11 and exclusion criteria and determining if the patient
12 was eligible.
13 Q Did you enroll every patient that was
14 eligible for the 2013 MSI-high study?
15 MS. BROWN-MARSHALL: Object to the form of
16 the question.
17 A So patients enroll in the study. Doctors
18 don't enroll in studies. So I would present a
19 patient that was eligible for the study with the
20 opportunity to enroll in the study. I would give
21 them an informed consent. I would then ask them to
22 read the informed consent. I would then answer any

1 questions that they had about the informed consent.
2 And if they were interested and eligible, we would
3 then enroll them in the study.
4 Q Did you present the 2013 MSI-high study to
5 every patient that was eligible for it?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A I believe not. It's hard for me to say.
9 You know, I presented it to the eligible patients
10 that I saw in clinic. But there were many other
11 patients seen at Ohio State by other GI oncologists
12 and I don't know what they did.
13 Q During the course of the 2013 MSI-high
14 study, when you saw a colorectal cancer patient,
15 would you always present the 2013 MSI-high study as
16 an option?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A So, again, presenting a study to a patient
20 requires a complicated number of assessments; one of
21 them is eligibility, one is suitability. So, for
22 example, if you had a patient who is a homeless drug

1 addict, but was eligible for the study, because of
2 their psychosocial issues, you likely wouldn't
3 consider them to enroll in the study because they
4 would be unlikely to follow all the rules of the
5 study to have interpretable data at the end of their
6 course of treatment.
7 So not every patient is suitable for a
8 clinical trial and not every suitable patient for a
9 clinical trial agrees to go on it. If you look at
10 the statistics across the United States, less than 5
11 percent of cancer patients enroll in clinical trials.
12 So the vast majority of patients are never treated on
13 a clinical study.
14 Q Did you present the 2013 MSI-high study as
15 an option during the course of that study any time
16 you had a patient that was both eligible and suitable
17 for the study?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A In general, I would present every patient
21 that was eligible with that option, but I can't be
22 certain that I did that a hundred percent of the

1 time. Many times patients were referred to me from
2 outside the institution because other physicians knew
3 that we had access to pembrolizumab at a time when
4 access was severely limited. And so I would often
5 get patients, for example, from Mayo Clinic, that
6 patient is described by declaration who is sent for
7 me -- sent to me specifically for enrollment in the
8 study after having been managed at another center.
9 Q How many patients did you enroll in the
10 2013 MSI-high study?
11 MS. BROWN-MARSHALL: Object to the form of
12 the question.
13 A So to the best of my recollection, I had
14 four eligible patients enrolled in the study
15 personally.
16 Q How many of those four patients were
17 MSI-high?
18 A All of them.
19 Q You did not enroll any patients in the 2013
20 MSI-high study that were MSI-low, correct?
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A By the time we activated the study, the
2 accrual goal for MSS patients had already been met.
3 The reason for that is 85 to 90 percent of patients
4 with metastatic colorectal cancer are MSS and only 5
5 to 15 percent of patients with metastatic colorectal
6 cancer are MSI-high. So it was much easier to enroll
7 patients, essentially 1 out of every 10 would be
8 MSI-high, 9 out of 10 would be MSS.
9 And so it took a while for us to negotiate
10 with Hopkins to open the trial, in part because the
11 amount of money that they were willing to pay on a
12 per case basis was not sufficient to cover the costs
13 of the trial initially until they found some
14 subsequent additional funding.
15 Q And is that common for a trial to only
16 select patients for a subset of the cohorts at a
17 particular facility?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A So there's a type of trial called a basket
21 trial in which a particular treatment is given to a
22 particular population of patients and often it will

1 have multiple arms. Each of those arms will have an
2 accrual goal. As the accrual goal is met for an arm,
3 enrollment to that arm of the study will be closed,
4 but the remainder of the study arms that still have
5 open spots can continue accruing.
6 And so the trial that we're referring to
7 had three arms; an arm for microsatellite instability
8 high patients with colorectal cancer, an arm for MSS
9 colorectal cancer patients, and an arm for MSI-high
10 non-colorectal cancer patients, each had separate
11 accrual goals, and one arm could be closed while
12 others remained open if that particular arm was fully
13 accrued.
14 Q So the 2013 MSI-high study was a basket
15 trial?
16 (Simultaneous speaking.)
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 Dr. Goldberg, let me get my objection on
20 the record, please.
21 Object to the form of the question.
22 A So it would meet the definition of a basket

1 trial in that it had several different cohorts of
2 patients being treated with the same intervention.
3 Q When did Ohio State get the trial started?
4 A I'm uncertain --
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A I'm uncertain of that date.
8 Q You said you had four patients that you
9 personally enrolled. Were they all colorectal cancer
10 patients?
11 A Yes. That was the main population of
12 patients I saw.
13 Q You referenced earlier patients that were
14 referred to you by physicians at different hospitals.
15 Is that a separate population of patients or is that
16 part of the four that you're referring to?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A So as a well-known GI oncologist, I would
20 often have patients referred to me for second
21 opinions or for management of refractory disease that
22 came from across the country, when I was at Mayo

1 Clinic, from across the world.
2 I also would see patients from Columbus and
3 the surrounding environment who sought me out as
4 their first or only oncologist and I took primary
5 care of them. Some of my referral patients I would
6 see at intervals, but they would get their treatment
7 at home. They would come to see me when there was a
8 question about whether to continue a treatment or a
9 need to change to a different treatment.
10 So my practice consisted of some oncology
11 patients for which I was the primary oncologist and
12 some for which I was the consulting oncologist.
13 Q I'm referring specifically, Dr. Goldberg,
14 to your answer earlier when I asked you whether you
15 presented the 2013 MSI-high study as an option,
16 during the course of that study any time you had a
17 patient that was both eligible and suitable, and in
18 response you pointed out how many times patients were
19 referred to you from outside the institution by other
20 physicians.
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A Well, I can't honestly say that I would
2 have offered the study to every single patient. But
3 it was an interesting study and an unmet need, and so
4 I believe I would offer it to anybody who I thought
5 was eligible. But I'm trying to remember back eight
6 or nine years ago.
7 Q Why did you think it was an interesting
8 study?
9 A You know, the information about the one
10 patient of 33 in the Topalian study who responded
11 with colorectal cancer to nivolumab and had a
12 sustained and complete response was highly engaging.
13 The data that Dr. Vogelstein in his
14 laboratory had put together suggesting that this
15 cohort of patients could have a response to a PD-1
16 inhibitor made scientific sense. We didn't know
17 whether what made scientific sense as a hypothesis
18 would prove to be real when humans were treated with
19 the agent.
20 There was a great unmet need for helping
21 patients with MSI-high cancers and also patients with
22 MSS cancers, but this study only applied to a subset

1 of those patients. And as I mentioned, an
2 opportunity to collaborate with the world-class
3 scientists at Hopkins would be appealing to any
4 cancer researcher.
5 Q While you were involved in the 2013
6 MSI-high study, you never had to consider whether to
7 recommend the study to a patient with MSS cancer,
8 correct?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A So as I stated, by the time we got the
12 study open, the MSS cohort was fully accrued and we
13 did not have the opportunity to enroll MSS patients
14 in the study.
15 Q Was the MSI-high -- let me rephrase.
16 Were the MSI-high cohorts ever closed in
17 the same manner as you described for the MSS cohort?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A So the study eventually met its accrual
21 goals and the trial was closed.
22 Q Swim Across America provided funding for

1 the 2013 MSI-high study, correct?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A According to what I was told by the Hopkins
5 investigators, and what's disclosed in the New
6 England Journal of Medicine article, that's true.
7 Q Do you know whether Swim Across America
8 funds every cancer trial that it's presented with?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A I have no knowledge of how Swim Across
12 America decides whether or not to fund studies.
13 Q MSI-high cancer is a relatively rare form
14 of cancer, correct?
15 MS. BROWN-MARSHALL: Object to the form of
16 the question.
17 A So colon cancer is a heterogeneous disease.
18 There are different driver mutations that occur, and
19 in some cases we don't know what the driver mutation
20 is that occurs.
21 One subset of colorectal cancer is driven
22 by a defect in mismatch repair. That is indicated by

1 microsatellite instability. It's estimated that in
2 advanced cancer, 5 to 15 percent of colorectal cancer
3 patients will be MSI-high. In earlier stages of
4 cancer, it's estimated to be 5 percent or less.
5 Q And you would agree that MSI-high
6 colorectal cancer subtype of cancer is relatively
7 rare, correct?
8 A It's relatively rare as opposed to MSS
9 patients. It's essentially 1 out of 10 patients with
10 metastatic colorectal cancer is MSI-high. If that --
11 if you define that as relatively rare, then it meets
12 the definition.
13 Q Well, would you agree that, in your
14 understanding of what people in the art consider
15 relatively rare to mean, that terminology would be
16 applicable?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A So to me, that's a bit of a vague question.
20 I could answer the question by saying there are rare
21 alterations that drive colon cancer, such as NTRK
22 mutations, that's about 2 percent of patients. About

1 3 percent of patients have a mutation in HER2. 5 to
2 15 percent of patients have MSI-high tumors than --
3 that's less rare than some of these other mutations
4 that are still relevant in management for colorectal
5 cancer patients.
6 Q Dr. Goldberg, can you turn to paragraph 55
7 of your declaration.
8 A I can. I have it in front of me.
9 Q If you look to the fourth line from the
10 bottom, you testify, "To speed accrual in a group of
11 patients with a relatively rare subtype of cancer,
12 MSI-high tumors, they also recruited teams at
13 collaborating institutions, including my own,"
14 correct?
15 A Correct.
16 Q So you would agree that MSI-high cancer is
17 a relatively rare subtype of cancer, correct?
18 A As I so stated.
19 Q Because MSI-high cancer is relatively rare,
20 patients for the MSI-high cohorts of the 2013
21 MSI-high study would have been tested for MSI-high
22 before being put into those cohorts, correct?

1 MS. BROWN-MARSHALL: Object to the form of
2 the question.
3 A The answer to that is no.
4 Q How would a patient with MSI-high cancer
5 have been placed into the MSI cohorts of the 2013
6 MSI-high study without being tested for MSI-high?
7 MS. BROWN-MARSHALL: Object to the form of
8 the question.
9 A So in all three arms, arms A, B and C were
10 open, patients were allowed to enroll in the study
11 whether they were MSI-high or MSS. And because the
12 treatment was the same regardless of whether they
13 were MSI-high or MSS, patients could be enrolled in
14 the study without knowledge of their microsatellite
15 instability status and would be assigned to the
16 correct arm of the study only after their tumors have
17 been tested for microsatellite instability until such
18 time as the MSS cohort in the basket study had met
19 its full accrual goals.
20 After that, in order to be eligible for the
21 study, a colorectal cancer patient had to be known to
22 be MSI-high and a non-colorectal cancer patient had

1 to be known to be MSI-high. But at the time that the
2 study initially opened, accrual could proceed before
3 MSI status was known.
4 Q Dr. Goldberg, are you reading from a
5 document?
6 A No. But I'm trying to be articulate.
7 Q Dr. Goldberg, you said that such a process
8 could happen. Are you saying that the process you
9 just described is what happened for the 2013 MSI-high
10 study?
11 MS. BROWN-MARSHALL: Object to the form of
12 the question.
13 A So I would refer you to Nils' expert
14 testimony, which discusses this in detail.
15 Q What do you mean by that, Dr. Goldberg?
16 A Exactly what I said; he had a detailed
17 report of this in his declaration.
18 Q Was Dr. Lonberg involved in the 2013
19 MSI-high study?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A I don't know if he was involved in it or

1 not.
2 Q So what was the basis for the answer you
3 provided me a moment ago about how patients could
4 have been enrolled into the 2013 MSI-high study
5 without having been tested for their MSI-high status?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A So it comes from reading the protocol and
9 from reading the declaration about the protocol that
10 Nils did.
11 Q What protocol are you referring to,
12 Dr. Goldberg?
13 A The protocol written by The Johns Hopkins
14 University group that provided the guidelines for the
15 study that we participated in and which was reported
16 in the New England Journal of Medicine, that protocol
17 was filed with the National Cancer Institute
18 ClinicalTrials.gov, and I believe it's an appendix to
19 the New England Journal of Medicine article.
20 Q Where do you cite to the protocol you're
21 referring to in your declaration?
22 A I'm not sure if I cited it, but it's the

1 study that the protocol I'm talking about is the NCI
2 number that we looked up earlier, which I would have
3 to look up. I'm not sure what page it's on. What
4 you've been referring to as the Hopkins MSI study.
5 Q Did you review Dr. Lonberg's declaration in
6 preparation for today's deposition, Dr. Goldberg?
7 A I did.
8 Q Do you have it with you today?
9 A I do not.
10 Q And when you're referring to a declaration
11 by Dr. Lonberg, do you know which declaration you're
12 referring to?
13 A I only know of one declaration that was
14 provided to me by the Fish attorneys.
15 Q And it was provided to you before you
16 prepared your declaration?
17 A No. It was provided to me within the last
18 couple weeks, long after I had signed the
19 declaration.
20 Q So are you saying that the protocol was
21 written in such a way that it said no MSI-high
22 testing was necessary until a cohort closed, and

1 after that MSI-high testing was necessary?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A So the protocol is a written document.
5 Rather than me speculating on what it says, why don't
6 we look at it.
7 Q Well, you told me a moment ago that your
8 answer was based on the protocol and you were
9 familiar with it. Are you no longer sure about how
10 the cohorts were filled?
11 MS. BROWN-MARSHALL: Objection to the form
12 of the question.
13 A Well, you keep asking me the same question.
14 I keep giving you the same answer. It is likely that
15 we could resolve it objectively if we looked at the
16 protocol. But if you keep asking me the question,
17 I'll keep giving you the same answer.
18 Q And what is that answer, Dr. Goldberg?
19 A Ask me the question.
20 Q Are you saying that the 2013 MSI-high study
21 was conducted such that initially no MSI-high testing
22 was conducted prior to placing patients into

1 respective cohorts and testing was only required
2 after the MSS cohort closed?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A So that's a very complicated question, and
6 in the end I'm going to say no to it because I
7 believe I could say yes if you split it into parts,
8 but no when you combine it all together. Perhaps you
9 should split your question into parts and I'll
10 address each one individually.
11 Q Let's actually circle back to something you
12 said a little while ago, Dr. Goldberg. You said that
13 a patient could be placed into a respective cohort
14 without previously having been tested for their
15 MSI-high status, correct?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A That's my understanding, yes.
19 Q I understand how you can say a patient
20 would have been enrolled in the study before being
21 tested for MSI-high status.
22 How could a patient have been possibly

1 placed into a cohort without knowing their MSI-high
2 status?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A So as I stated, the treatment with
6 pembrolizumab for cohorts A and B was the same, and
7 so it wasn't necessary to know the MSI-high status at
8 the time of enrollment and initiation of treatment.
9 It was necessary to know the MSI-high
10 status to correctly assign the patient to the MSS or
11 MSI-high cohort. But that could be done after the
12 patient signed consent after they initiated
13 treatment, because it didn't make a difference in
14 terms of treatment, but it did make a difference in
15 terms of which group their outcomes would be analyzed
16 in.
17 Q What if there was an adverse reaction to
18 one of the cohorts?
19 MS. BROWN-MARSHALL: Object to the form of
20 the question.
21 A So you mean an adverse reaction to the
22 pembrolizumab?

1 Q If Merck or JHU determined that one of the
2 cohorts was particularly susceptible to an adverse
3 reaction, under the understanding of the protocol
4 that you've laid out, they wouldn't be able to deal
5 with that, correct?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A I don't understand your question. If a
9 patient had an adverse reaction, the protocol had
10 specifications on how to manage it, overseen by
11 Dr. Le. And it wouldn't have mattered whether they
12 were MSI-high or MSS; it would be managed the same
13 way for adverse reactions regardless of that.
14 Q I'm going to share on the screen,
15 Dr. Goldberg, what has been previously marked as
16 Exhibit 1064.
17 MS. BROWN-MARSHALL: Counsel, is this
18 exhibit also going to appear in the folder link in
19 the chat?
20 MR. ZEILBERGER: We can put it there.
21 MS. BROWN-MARSHALL: That would be helpful.
22 Thank you.

1 THE TECHNICIAN: This is the remote
2 technician. Counsel, is that something you're
3 sharing on your own screen? I do not have a 1064.
4 MR. ZEILBERGER: Yes, we're going to share
5 that now.
6 THE TECHNICIAN: Thank you.
7 BY MR. ZEILBERGER:
8 Q Can you see my screen, Dr. Goldberg?
9 A I do.
10 Q Do you see a PDF document that has a title
11 "Supplemental Appendix" and at the bottom right it
12 says Exhibit 1064?
13 A I see that.
14 Q And on the cover page of Exhibit 1064 it
15 says it is a supplement to Le, et al., PD-1 blockade
16 in tumors with a mismatch-repair deficiency, New
17 England Journal of Medicine 2015?
18 A I see that.
19 Q And is this the supplement to the New
20 England Journal of Medicine article that you were
21 referring to earlier today?
22 A I can't tell yet what the text is about. I

1 can only see the title.
2 Q Sure. Turning to the next page, do you see
3 the table of contents of this document?
4 A I do.
5 Q Do you have an understanding from the table
6 of contents what this document is?
7 A My understanding is that this is not the
8 clinical trial protocol, but, rather, a summary of
9 the overall study design and some of the results of
10 the study.
11 Q Do you have an understanding as to whether
12 this document accurately reflects the design of the
13 study?
14 MS. BROWN-MARSHALL: Object to the form of
15 the question.
16 A I have not had an opportunity recently to
17 review this supplementary appendix. When I look at
18 the table of contents, all I see is Figure S1 is
19 overview of study design. I assume that that is just
20 a short summary in figure form of the study design,
21 not an explication of the entire protocol.
22 Q Would you or other authors on the New

1 England Journal of Medicine article have submitted a
2 supplement to that article that is not accurate?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A I certainly wouldn't have submitted
6 something that was inaccurate. But I cannot
7 guarantee that something inaccurate wasn't presented
8 by somebody else.
9 Q Turning to the fourth page of the PDF, it's
10 numbered page 3 at the bottom -- can you still see my
11 screen?
12 A I can.
13 Q Do you see how the second sentence under
14 the header Patients says "All patients underwent MRR
15 status testing prior to enrollment"?
16 A Let me just read that.
17 So I see that, but that is different than
18 what I understood.
19 Q The explanation about patients undergoing
20 MMR status testing prior to enrollment is
21 inconsistent with the understanding you had when you
22 prepared your declaration. Is that right?

1 MS. BROWN-MARSHALL: Object to the form of
2 the question.
3 A So it does not state here that all
4 patients' MMR status was known at the time that they
5 were enrolled. And that was my understanding, was
6 that patients could be enrolled regardless of whether
7 they were known to be MSI-high or MSS.
8 Q So you're saying that patients would have
9 been tested prior to enrollment, but the results of
10 that test wouldn't have been looked at --
11 MS. BROWN-MARSHALL: Object to the form of
12 the question.
13 Q -- until after the patients were placed
14 into the cohort?
15 MS. BROWN-MARSHALL: Object to the form of
16 the question.
17 A So I don't see in this paragraph that it
18 states that patients were -- had to be assigned to
19 cohort A or cohort B prior to enrollment.
20 What it states here is an MMR status was
21 tested. It doesn't say that it was used to assign
22 the patients to arm A or arm B.

1 It seems like we have a pause here. In the
2 next few minutes I would like to request that we take
3 another break.
4 Q Sure, we can take a break.
5 (Recess 11:10 a.m. - 11:17 a.m.)
6 BY MR. ZEILBERGER:
7 Q Dr. Goldberg, your opinions in your
8 declaration are based on the understanding the
9 priority date of the '393 patent is July 10th, 2015,
10 correct?
11 A Correct.
12 Q Do you understand what a priority date is?
13 A I believe so. But would you like to
14 explain it to me?
15 Q I would like to know your understanding of
16 what a priority date is, Dr. Goldberg.
17 A So my understanding is that the priority
18 date is the initial registration of an intent to
19 patent an idea that sort of plants a flag in the sand
20 stating that this idea is an invention that we intend
21 to submit a patent for.
22 Q Before the alleged priority date of the

1 '393 patent, immuno-oncology agents were in
2 development by laboratory and clinic-based research
3 teams, correct?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A Correct.
7 Q Why were immuno-oncology agents being
8 developed?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A You would have to ask the companies that
12 were putting resources into doing that.
13 Q So you have no knowledge as to why before
14 the alleged priority date of the '393 patent
15 immuno-oncology agents were being developed?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A So the answer to your question is no.
19 Q So what is your understanding?
20 A Well, we don't --
21 MS. BROWN-MARSHALL: Sorry. Object to the
22 form of the question.

1 A So there has been a tremendous interest
2 over many years of trying to harness the immune
3 system to kill cancer cells and decades of work and
4 hundreds of careers have been devoted to trying to do
5 that.
6 Up until the time that nivolumab was found
7 by BMS investigators to be effective in some cancers,
8 this work had largely been done in vain. Once there
9 was a breakthrough with the findings about nivolumab
10 being able to uncloak tumors so that T cells could
11 recognize them as foreign and destroy them, there was
12 an intense interest in the possibility of harnessing
13 the immune system by developing additional PD-1
14 inhibitors, PD-L1 inhibitors, CTLA-4 inhibitors, and
15 other immunomodulating treatments in order to
16 potentially further the ability to exploit innate
17 immunity to destroy cancer cells. And so companies
18 all over the world began more aggressively
19 researching immuno-oncology opportunities once the
20 first breakthrough had occurred.
21 Q And you understand that this first
22 breakthrough you are referring to involving nivolumab

1 occurred before the alleged priority date of the '393
2 patent, correct?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A I know that nivolumab was approved for
6 indications prior to 2015.
7 Q When you refer to a first breakthrough
8 involving nivolumab, what are you referring to?
9 A Well, as I understand it, it was the first
10 PD-1 inhibitor that showed activity, it showed
11 activity in a number of different cancer types
12 originating from different organs and it led to a
13 patent and an FDA indication in several tumor types.
14 Q We looked at a little earlier today at
15 paragraph 11 of your declaration, footnote 2 you
16 refer to Exhibit 1005 to this proceeding, correct?
17 A Give me a moment, please.
18 Okay. So I have paragraph 11 in front of
19 me. Please repeat your question.
20 Q In footnote 2 to paragraph 11 you refer to
21 Exhibit 1005, correct?
22 A Correct.

1 Q And that is the MSI-high study record
2 publicizing the 2013 MSI-high study, correct?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A So this references to the posting on
6 ClinicalTrials.gov of Trial NCT01876511. That
7 posting is required by the federal government for any
8 clinical trials that are underway in the United
9 States, so that's my understanding of what that
10 footnote refers to.
11 Q Is ClinicalTrials.gov a secret website?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A Frankly, that seems like a ridiculous
15 question. It's ClinicalTrials.gov, it's open to
16 anybody who puts ClinicalTrials.gov into their
17 browser.
18 Q And it's fair to say that postings on
19 ClinicalTrials.gov are publicly available. Yes?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A As I stated, anybody who puts

1 ClinicalTrials.gov into their website -- their web
2 browser, can go to that site.
3 Q And do you have Exhibit 1005 available to
4 you right now?
5 A I don't have it. I don't know if Casey has
6 it.
7 Q It should be in the folder that we've
8 uploaded materials to, if it can be downloaded.
9 THE TECHNICIAN: This is the remote
10 technician. Doctor, if you click on the link in the
11 chat, that should take you to a browser window and
12 the file should be available there.
13 A Okay. So I have clicked on that Planet
14 Depos website and I see four PDFs. Which one are we
15 referring to? Or three PDFs.
16 Q It should be labeled Exhibit 1005.
17 A I don't see that labeling.
18 THE TECHNICIAN: It may start with
19 IPR202400240 and then EX1005.
20 THE WITNESS: Okay. Now I see it. Thank
21 you. So it's loading.
22 A Okay. I have that in front of me now.

1 Q If you can please turn to page 3 of Exhibit
2 1005.
3 A Okay. I'm on page 3.
4 Q On page 3 Exhibit 1005 teaches that a study
5 would be conducted to examine whether pembrolizumab
6 is effective and safe in treating patients with MSI
7 positive colon cancer, correct?
8 MS. BROWN-MARSHALL: Objection; mischaracterizes
9 the document.
10 A Well, I see the brief summary. I'll read
11 what it says on the brief summary.
12 It says, "This study will be looking at
13 whether MK-3475 (an antibody that blocks negative
14 signals to T cells) is effective (anti-tumor
15 activity) and safe in three different patient
16 populations. These include patients with MSI
17 positive colon cancer, patients with MSI negative
18 colon cancer, and patients with other MSI positive
19 cancers." That's what I see on this page.
20 Q In preparing your declaration, did you
21 analyze what had been published in the art before the
22 alleged priority date of the '393 patent regarding

1 the treatment of MSI-high cancer with immunotherapy
2 including anti-PD-1 drugs?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A So I can't say that I read every bit of
6 literature that had ever been published with regard
7 to the use of PD-1 inhibitors in the treatment of
8 cancer. I did read selected references.
9 Q Did you identify the references that you
10 reviewed or were they provided to you?
11 A I did PubMed searches of relevant articles
12 and considered those articles in formulating my
13 declaration. I cited the ones that I specifically
14 drew information from in the declaration.
15 Q When preparing your declaration, were you
16 aware that before July 10th, 2015, including in 2014,
17 there was published literature recognizing that
18 effective immunotherapy for the treatment of
19 colorectal cancer may be used in the near future?
20 MS. BROWN-MARSHALL: Objection to the form
21 of the question.
22 A So I don't really know how to answer that

1 question. Was I aware that people thought that
2 immunotherapy might work in cancer? Yes. That it
3 might work in colon cancer? Yes. Was I aware of any
4 data that it worked in colon cancer? No.
5 Q Were you aware that before July 10th, 2015,
6 including in 2014, there was published literature
7 recognizing that colorectal cancers associated with
8 microsatellite instability were good candidates for
9 immunotherapy?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A So I think somebody could have speculated
13 that they were good candidates for immunotherapy.
14 But until you do the experiment of treating human
15 patients with immuno-oncology drugs, all that is is
16 speculation.
17 Q I'm asking you, Dr. Goldberg, if you were
18 aware of such publications when preparing your
19 declaration.
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A Not that I recall.

1 Q And so you didn't consider any such
2 publications when you prepared your declaration,
3 correct?
4 MS. BROWN-MARSHALL: Objection; outside the
5 scope of the declaration.
6 A So I'm not sure I really understand your
7 question. Could you restate it, please?
8 Q When you prepared your declaration for this
9 proceeding, were you aware that before July 10th,
10 2014 -- 2015, including in 2014, there was published
11 literature recognizing that colorectal cancers
12 associated with microsatellite instability were good
13 candidates for immunotherapy?
14 MS. BROWN-MARSHALL: And I'm going to
15 object, again, as outside the scope of the
16 declaration.
17 A So I was not aware that there was any data
18 -- (technical interruption).
19 MR. ZEILBERGER: I can no longer hear
20 Dr. Goldberg. I don't know if other people can.
21 MS. BROWN-MARSHALL: No, counsel. I think
22 the screen froze.

1 MR. ZEILBERGER: Okay. Why don't we go off
2 the record while those technical issues are being
3 resolved for Dr. Goldberg.
4 MS. BROWN-MARSHALL: I think they're back.
5 THE WITNESS: Okay. So I can see you and I
6 can hear you. I don't know if you can hear me.
7 MR. ZEILBERGER: I can hear you now,
8 Dr. Goldberg. And I think likely the vast majority
9 of your answer was cut off, so I'll re-ask the
10 question.
11 THE WITNESS: Okay.
12 BY MR. ZEILBERGER:
13 Q When you prepared your declaration for this
14 proceeding, were you aware that before July 10th,
15 2015, including in 2014, there was published
16 literature recognizing that colorectal cancers
17 associated with microsatellite instability were good
18 candidates for immunotherapy?
19 MS. BROWN-MARSHALL: Objection; outside the
20 scope of the declaration.
21 A So I was not aware of any data that showed
22 that any immuno-oncology intervention was effective

1 against colorectal cancer, whether it was MSI-high or
2 MSS, and I was not specifically aware of any
3 speculation that it was likely to be a good candidate
4 for that.
5 Q Are you familiar, Dr. Goldberg, with the
6 World Journal of Gastroenterology?
7 A I didn't get all of your question. All I
8 heard was "World Journal of Gastroenterology."
9 Q I'll repeat the question. Are you familiar
10 with the World Journal of Gastroenterology?
11 A I have not read that journal, so I believe
12 it may exist, but I have not looked at it
13 specifically.
14 Q And in preparing your declaration, you
15 weren't provided any materials from the World Journal
16 of Gastroenterology for consideration. Is that
17 right?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A Not that I recall.
21 Q Do you recall if you reviewed any
22 literature published by Dr. Brunet (phonetic)?

1 MS. BROWN-MARSHALL: Object to the form of
2 the question.
3 A That name is not familiar to me.
4 Q Were you aware that before July 10th, 2015,
5 including in 2014, there was published literature
6 recognizing that anti-PD-1 or PD-L1 antibodies are
7 emerging as promising anti-cancer therapeutics?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So I had not read any literature that I
11 recall that promoted that idea.
12 Q In preparing your declaration, did you
13 review any literature by Dr. Champiat?
14 A The name doesn't seem familiar to me. I
15 can't remember the author's names of every bit of
16 literature that I reviewed. But I don't remember
17 that one specifically.
18 Q Is it fair to say that if you had been
19 aware of literature recognizing that anti-PD-1
20 antibodies are emerging as promising anti-cancer
21 therapeutics, you would have addressed it in your
22 declaration?

1 MS. BROWN-MARSHALL: Objection to the form
2 of the question and outside the scope of the
3 declaration.
4 A It's hard for me to answer that question;
5 it's a hypothetical question. And, you know, I know
6 what I did to prepare for my declaration and I
7 believe I was thorough in my preparations.
8 Q When you referred to data earlier, that you
9 hadn't been aware of any data relating to the use of
10 anti-PD-1 drugs for MSI-high cancer, what are you
11 referring to by "data"?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A Well, there certainly was no human data
15 that I was aware of.
16 One of the difficulties in the development
17 of immuno-oncology drugs is that mouse models, which
18 traditionally can be used for other classes of drugs,
19 such as cytotoxics, are not relevant because the
20 human immune system is peculiar to the human species.
21 And so I wasn't aware of any preclinical data and I
22 wasn't aware of any human clinical trial data.

1 The difficulty with immuno-oncology agents
2 is that they have to be tested in humans because
3 there are no laboratory models that predict how
4 humans will respond to this class of drugs.
5 Q So are you saying that without any human
6 data, all potential treatments are on equal footing?
7 MS. BROWN-MARSHALL: Object to the form of
8 the question.
9 A I don't know how to answer that question.
10 I guess the answer would be no, because you're saying
11 all human -- all treatments would be on the same
12 footing. Obviously that's not the case.
13 Q What would make somebody want to conduct a
14 clinical trial involving a particular anti-PD-1 drug?
15 MS. BROWN-MARSHALL: Object to the form of
16 the question.
17 A That's an incredibly broad question. I'll
18 answer it with a broad answer. We don't cure cancer
19 in all patients, and, therefore, people who are
20 studying cancer are motivated to test every avenue
21 that they can to try and improve the outcomes for our
22 patients.

1 Q There is -- there are non-human
2 trial-related reasons why a scientist would want to
3 focus on a particular drug for a clinical trial,
4 correct?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A I'm finding your questions very hard to
8 answer because they're very convoluted and they seem
9 off topic to me. Perhaps I'm missing something.
10 You're certainly not referencing my declaration
11 anymore, which is what I thought we were here to do.
12 Q I would appreciate it, Dr. Goldberg, if you
13 could just answer my questions.
14 A Well, I would appreciate it if you would
15 ask me questions that were answerable.
16 Q Is it your opinion that without human data,
17 all drugs are equally speculative in terms of whether
18 they will be effective?
19 MS. BROWN-MARSHALL: Objection; outside the
20 scope of the declaration.
21 A No.
22 Q What will make a drug -- strike that.

1 Were you aware that before July 10th, 2015,
2 including in 2014, there was published literature
3 observing that emerging data confirmed that
4 colorectal cancer is a heterogeneous group of tumors
5 that can be divided -- subdivided by their molecular
6 features and treated differently, including based on
7 a tumor's status as microsatellite instable versus
8 microsatellite stable?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A Can you break that question up into single
12 clauses that I can respond to? Because, you know, I
13 have -- it's hard for me to respond to a complicated
14 question like that with a cogent answer.
15 Q Were you aware that before July 10th, 2015,
16 including 2014, there was published literature
17 observing that emerging data confirmed that
18 colorectal cancer is a heterogeneous group of tumors
19 that can be subdivided by their molecular features?
20 A Yes, I'm aware of that.
21 MS. BROWN-MARSHALL: Objection.
22 Q Were you aware that before July 10th, 2015,

1 including in 2014, there was published literature
2 observing that emerging data confirmed that
3 colorectal cancer could be treated based on a tumor's
4 status as a microsatellite instable versus
5 microsatellite stable?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A So the data that I'm aware of was that in
9 my clinical practice I treated patients at that time
10 regardless of their microsatellite instability or
11 stability with the same drug and the same drug
12 strategies.
13 So even though it was known in 2015 that
14 MSI-high tumors often were less responsive to
15 conventional chemotherapy and existing targeted
16 therapies, there were no alternatives to using those
17 existing chemotherapies and targeted therapies. So
18 patients with MSI -- MSI status of a tumor was
19 irrelevant to treatment decisions at that time.
20 Q Were you aware that before July 10th, 2015,
21 including in 2014, there was published literature
22 observing that as a result of the intriguing data

1 from the nivolumab CRC study, clinical trials of
2 anti-PD-1 agents were underway in patients with
3 MSI-high colorectal tumors?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A Well, obviously I was aware that clinical
7 trials were in progress for MSI-high -- for MSI-high
8 colorectal cancer patients because I was
9 participating in one.
10 Q Were you aware that there was literature
11 specifically referencing intriguing data from the
12 nivolumab colorectal cancer study?
13 MS. BROWN-MARSHALL: Object to the form of
14 the question.
15 A So one of the major references that I was
16 aware of was the study published in the New England
17 Journal, Topalian, which is referenced in my
18 declaration, reporting on the experience of close to
19 300 patients treated with nivolumab having different
20 types of cancers. And I'm aware that of the patients
21 with colorectal cancer cited in her New England
22 Journal article there were no responses.

1 I was also aware of the fact that some
2 additional patients with colorectal cancer were
3 treated with nivolumab, and of the 33 colorectal
4 cancer patients treated, there was one response.
5 So that's the knowledge that I have
6 regarding the efficacy of nivolumab in colorectal
7 cancer up until that time.
8 Q When you prepared your declaration, were
9 you aware of literature hypothesizing that tumors
10 deficient in mismatch repair may be particularly
11 sensitive to immunotherapy given an ongoing
12 accumulation of mutations at a high frequency?
13 MS. BROWN-MARSHALL: Object to the form of
14 the question.
15 A So I was aware that mismatch repair defects
16 that are indicated by microsatellite instability
17 result in mutations in patients with mismatch repair
18 deficient tumors. I was not aware that there was any
19 data showing that that led to efficacy in human
20 trials up until the Le study.
21 Q So I'm going to share in the chat a file
22 Exhibit 1115, and I'll note this is a new exhibit and

1 we have labeled it as Exhibit 1115 for purposes of
2 this deposition.
3 Please let me know when you have it,
4 Dr. Goldberg.
5 A So when I opened the file I couldn't find
6 it, so I'm going to refresh and see if it comes up
7 now.
8 Q Sure.
9 A So I see three exhibits; one is called Test
10 Exhibit, one is 1005, that we've already talked
11 about, and the other is 2090. Those are the three
12 things that I can see in my chat. I believe that's
13 not -- none of those three are the things -- is the
14 file that you would like me to look at.
15 Q I think the tech on the line is going to
16 help you get access to it.
17 THE TECHNICIAN: Yes, sir. If you refresh
18 your page, it should show up for you. If it's a
19 large file; it may take a moment.
20 A So I just closed the exhibits and went back
21 to the chat and reopened Exhibits 12, 13, 20, 24.
22 I'll do that again. Okay. Now there's a fourth file

1 which is 1115. Is that the one that you would like
2 me to open?
3 Q That's right.
4 A Okay. All right. I have that file open.
5 Q This document is titled "Recent Therapeutic
6 Advances in the Treatment of Colorectal Cancer,"
7 correct?
8 A That's what it says.
9 Q Do you recognize this article?
10 A I do.
11 Q You are a co-author on this article,
12 correct?
13 A Correct.
14 Q And on the cover page it indicates that
15 this first published in a review in Advance on
16 October 9th, 2014, correct?
17 A Yes, I see that.
18 Q Can you please turn to the second page of
19 this PDF.
20 A Okay. That's page 2 of 13.
21 Q Correct. In the introduction to Exhibit
22 1115 it says that "The Cancer Genome Atlas project

1 and other efforts, discovery of new predictive
2 biomarkers from clinical studies, and novel targeted
3 agents introduced into clinical practice. Emerging
4 data confirm that CRC, despite similar histology
5 across cases, is a heterogeneous group of tumors that
6 can be subdivided by their molecular features and
7 treated differently, e.g., microsatellite instable
8 versus microsatellite stable," correct?
9 MS. BROWN-MARSHALL: Objection;
10 mischaracterizes the document.
11 A I see the statement that you're making.
12 Q What emerging data referenced in the
13 introduction of this article that you co-authored
14 were you referring to?
15 A So, clearly, the heterogeneity of
16 colorectal cancer was something that was increasingly
17 well-understood around 2014 when this was discovered.
18 Some of the different drivers of colorectal cancer
19 included microsatellite instability, RAS mutation,
20 RAF mutation, PI3 kinase mutations. Some of those
21 were amenable to treatment with specific targeted
22 drugs; some were not.

1 And I think that this sentence talks about
2 two things; heterogeneity and treatment distinctions.
3 But not every one of the items listed under -- after
4 the e.g. applies to both heterogeneity and
5 differences in treatment. And microsatellite
6 instability was not relevant to treatment decisions
7 until after the discoveries by the Hopkins group.
8 Q And when you say after the discoveries of
9 the Hopkins group, are you referring to a discovery
10 on July 10th, 2015?
11 MS. BROWN-MARSHALL: Object to the form of
12 the question.
13 A I'm referring to the discoveries made by
14 the completion of the Hopkins trial that Dr. Le was
15 running that we've been discussing in detail today.
16 Q You said that microsatellite instability
17 was not relevant to treatment decisions until after
18 the discoveries by the Hopkins group. Would you
19 agree that microsatellite instability was relevant in
20 considering potential treatments to be explored for
21 microsatellite instable colorectal cancer?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A Can you please (technical interruption.)
3 MR. ZEILBERGER: I think we've lost
4 Dr. Goldberg again. Counsel?
5 MS. BROWN-MARSHALL: Yeah, I'm here. I
6 can't see them either.
7 MR. ZEILBERGER: Okay. Let's go off the
8 record while this is worked out.
9 (Pause in proceedings.)
10 BY MR. ZEILBERGER:
11 Q Dr. Goldberg, can you hear me now?
12 A I can.
13 Q You said earlier that microsatellite
14 instability was not relevant to treatment decisions
15 before the alleged priority date of the '393 patent,
16 correct?
17 A Yes.
18 Q Would you agree that microsatellite
19 instability was relevant prior to the alleged
20 priority date of the '393 patent in considering
21 potential treatments to explore with clinical trials
22 for microsatellite instable colorectal cancer?

1 MS. BROWN-MARSHALL: Object to the form of
2 the question.
3 A So I would say that experiments testing new
4 treatments and new combinations of treatments for
5 microsatellite unstable tumors in patients was an
6 unmet medical need that needed further investigation.
7 I'm not sure if I'm answering your
8 question, but your questions are hard to answer
9 because of so many dependent clauses.
10 Q What don't you understand about my
11 question, Dr. Goldberg?
12 A Well, can you -- can you simplify your
13 question so that it has a noun, a verb and a subject
14 without a bunch of dependent clauses in it? I'm
15 trying my best, but it's taxing to try and answer
16 questions that are made up of sentences that are 20
17 pages long with "ands" in the middle of them.
18 Q I'd like to help you, Dr. Goldberg, but --
19 maybe I can repeat my question and maybe you can tell
20 me what the clauses are that you're not
21 understanding. Is that okay?
22 A Let's try it and see if we can make it

1 work.
2 Q Would you agree that microsatellite
3 instability was a relevant factor prior to the
4 alleged priority date of the '393 patent in
5 considering potential treatments to explore with
6 clinical trials for microsatellite instable
7 colorectal cancer?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So I guess I'm going to say yes, and I'm
11 going to paraphrase my understanding that there were
12 unmet needs for the treatment of patients with
13 MSI-high tumors, and, therefore, it was useful to
14 explore new options for treatment for that group of
15 patients.
16 Q If you could turn to page 8 of 13 of
17 Exhibit 1115 and please let me know when you're
18 there.
19 A Okay. I'm on page 8.
20 Q At page 8 your article has a section titled
21 Immunotherapy in Colorectal Cancer, correct?
22 A Yes.

1 Q And the first sentence to that section
2 says, "Within oncology, perhaps the most exciting
3 current trend in developmental therapeutics is
4 immunotherapy," correct?
5 A I see that.
6 Q Why did you describe immunotherapy as
7 perhaps the most exciting current trend in
8 developmental therapeutics?
9 A So it was based primarily on the data from
10 the Topalian trial showing a high response rate in
11 patients with refractory melanoma, a high response
12 rate in patients with refractory non-small cell lung
13 cancer, responses in bladder cancer, Hodgkin's
14 lymphoma. Melanoma at that time was essentially
15 refractory to all other treatment options, including
16 cytotoxics and targeted therapy. And so to see a
17 double digit response rate in refractory patients in
18 that setting was extremely exciting but preliminary.
19 Q A little further in this paragraph of
20 Exhibit 1115 your article says, "Unfortunately,
21 immunotherapy in unselected patients with CRC has
22 been largely disappointing thus far. However, it may

1 be that selected CRC patients will benefit from
2 immunotherapy, and the challenge resides in
3 discovering predictive biomarkers for this group of
4 patients."
5 Do you see that?
6 A I do.
7 Q Why does the article say that it may be
8 that selected CRC patients will benefit from
9 immunotherapy?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A Because we believe that there was the
13 potential for immunotherapy to be effective. It just
14 hadn't been shown to be yet.
15 Q And was that understanding based on the
16 Topalian study?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A So I would like to go down to references 49
20 and 50 here. I don't remember what we cited as 49
21 and 50, but that's the reference for that. So these
22 references -- so 49 is a phase 1 study of single

1 agent PD-1 inhibitors in refractory solid tumors that
2 were published in the Journal of Clinical Oncology in
3 2010. And then durable cancer regression
4 off-treatment and effective reinduction therapy with
5 a PD-1 inhibitor from Cancer Research, published in
6 2013.
7 So this was preliminary data from phase 1
8 studies, and I don't recall whether there were colon
9 cancer patients included in these phase 1 -- in
10 references 49 and 50 without going back to the
11 papers.
12 Q You start the sentence that cites to
13 references 49 and 50 by referring to a patient with
14 refractory colorectal cancer, correct?
15 A Yes. And I believe that that may have been
16 the patient in the Topalian study, the 1 out of 33
17 that responded, but I'm not certain.
18 Q Nivolumab is an anti-PD-1 inhibitor,
19 correct?
20 A Yes, as stated in that sentence.
21 Q Based on the discussion in this paragraph
22 of Exhibit 1115, there was human data relating to

1 anti-PD-1 drugs for an MSI-high colorectal cancer
2 patient before July 10th, 2015, correct?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A So this paragraph references a single
6 patient who had a sustained and deep response to
7 nivolumab.
8 Q Is that not human data?
9 A That is human data.
10 Q Earlier today when you said that there was
11 not any human data before July 10th, 2015 relating to
12 the use of an anti-PD-1 drug for MSI-high colorectal
13 cancer, that was not correct, true?
14 MS. BROWN-MARSHALL: Objection;
15 mischaracterizes previous testimony.
16 A So this shows that there was data in one
17 patient.
18 Q And you also explain specifically in this
19 paragraph at page 8 of Exhibit 1115 that "Further
20 analysis demonstrated this patient's tumor manifested
21 high microsatellite instability with cell surface
22 expression of PD-L1 by infiltrating macrophages and

1 lymphocytes," correct?
2 A That's what it states and it references
3 reference 51.
4 Q And so you would agree that before the
5 alleged priority date of the '393 patent, it was
6 already publicly known that there was human data
7 showing a durable complete response in a patient with
8 MSI-high colorectal cancer through the treatment of
9 an anti-PD-1 inhibitor, correct?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A So in the Topalian trial it showed that
13 there was one patient of 33 who had responded to
14 nivolumab, so there was an N of one finding that a
15 single patient had responded to nivolumab at that
16 time and that's what led to the Hopkins study.
17 Q And it was also publicly known that that
18 patient had specifically MSI-high colorectal cancer,
19 correct?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A That's what it states in this article.

1 Q And that publicly known result is what led
2 you to say in this article that it may be that
3 selected colorectal cancer patients will benefit from
4 immunotherapy, correct?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A So that led us to speculate that it might
8 be true, but nobody had proven it. And I would
9 remind you that both Merck and BMS were given the
10 opportunities to support the Hopkins trial and they
11 didn't feel that this one person's response was
12 compelling enough to commit resources to test that.
13 Q The answer you just gave me, Dr. Goldberg,
14 that's not based on any personal knowledge of yours,
15 correct? That's based on what the JHU scientists
16 told you?
17 MS. BROWN-MARSHALL: Objection;
18 mischaracterizes previous testimony. Also asked and
19 answered.
20 A And it's based on what I read in the Forbes
21 article and the discussions that we have already
22 covered with the JHU scientists.

1 Q You had no involvement in any discussions
2 between JHU and Merck or JHU and BMS, correct?
3 A You asked me that question before and I
4 said no.
5 MS. BROWN-MARSHALL: Counsel, is now a good
6 time to take our lunch break?
7 MR. ZEILBERGER: Just a few more minutes,
8 if that's okay with Dr. Goldberg.
9 THE WITNESS: That's fine.
10 Q In the paragraph that we're on right now,
11 you say that "Given that immune checkpoint inhibitors
12 work best in tumors with high mutation burdens, it is
13 hypothesized that tumors deficient in mismatch repair
14 such as this patient's cancer may be particularly
15 sensitive to immunotherapy given an ongoing
16 accumulation of mutations at a high frequency,"
17 correct?
18 A Yes, I see that.
19 Q When you used the word "hypothesized"
20 there, is there a reason why you used the word
21 "hypothesized" and not "speculated"?
22 A Because by this time we were participating

1 in the Hopkins trial and the hypothesis of the
2 Hopkins trial is exactly as stated here.
3 Q You would agree, though, that there's a
4 difference in scientific literature between the word
5 "hypothesis" and "speculate," correct?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A So a hypothesis is a kind of speculation,
9 but it's a kind of speculation for which you can
10 design an experiment to provide an answer.
11 Q Would you agree that the hypothesis you're
12 referring to in Exhibit 1115 was based on at least
13 some data supporting the hypothesis?
14 MS. BROWN-MARSHALL: Object to the form of
15 the question.
16 A The hypothesis was based on the clinical
17 trial that we were participating in being run by
18 Hopkins, which was based on the response in one
19 patient in the Topalian trial, who was subsequently
20 found to be MSI-high.
21 Q When you say the word subsequently found to
22 be MSI-high, you do understand that it was publicly

1 known that that patient was MSI-high, correct?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A That is not my understanding. My
5 understanding is that Dr. Diaz speculated that that
6 patient was MSI-high. That patient was from Detroit.
7 They went back to the patient's physicians, asked for
8 a sample of the tumor. The tumor was then tested for
9 microsatellite instability. And as Dr. Diaz had
10 speculated, the patient was MSI-high, leading to the
11 development of a hypothesis that MSI-high tumors
12 might respond to PD-1 inhibitors and the development
13 of a clinical trial that we have been discussing
14 today.
15 Q So I'm going to share on my screen what's
16 been previously marked as Exhibit 1057, and the tech
17 can provide access to it to the extent you want to
18 see it, the full file, but it is part of the record.
19 A So that will just show on my screen? Or
20 what do I need --
21 Q Yeah, you should be able to see what I'm
22 sharing right now.

1 A On the Zoom screen, okay. So a paper by
2 the Hopkins group with the senior author being
3 Dr. Topalian.
4 Q And this is the -- one of the two articles
5 that you reference in your paper, correct?
6 A Correct.
7 Q And the first author is Dr. Lipson?
8 A I see that.
9 Q And if we scroll down to page 2 of 8, at
10 the bottom right of the screen there is a section
11 titled Durable complete response in colorectal
12 cancer. Do you see that?
13 A I see that.
14 Q And it describes a 71-year old colorectal
15 cancer patient who -- I'll stop there. Describes a
16 71-year old male with colorectal cancer, correct?
17 A I see that.
18 Q And at line 5 of that section, it
19 explicitly identifies that this patient had
20 microsatellite instability high genotype, correct?
21 A I see that, but it doesn't state when that
22 discovery was made.

1 Q Understood, Dr. Goldberg. But do you see
2 at the bottom right of the screen next to the page
3 number, that this exhibit, this article was published
4 on January 15th, 2013?
5 A I see that.
6 Q So as of January 2013, it would have been
7 publicly known that the patient in the nivolumab
8 study who had a complete response had MSI-high
9 colorectal cancer, correct?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A Correct.
13 MR. ZEILBERGER: Okay. Why don't we take a
14 break.
15 THE WITNESS: What time are we going to
16 resume?
17 MR. ZEILBERGER: We can go off the record.
18 (Recess 12:27 p.m. - 1:00 p.m.)
19 BY MR. ZEILBERGER:
20 Q Dr. Goldberg, looking back to Exhibit 1115,
21 do you have that?
22 A I have to pull it up again. That was the

1 one we were just working with, right?
2 Q The one just before the one we were looking
3 at most recently.
4 A Okay. So I have 1115 in front of me. We
5 were on page 8, correct?
6 Q Yes. Thank you. The last sentence in the
7 section directed to immunotherapy in colorectal
8 cancers says, "As a result of these intriguing data,
9 clinical trials of anti-PD-1 agents are currently
10 underway in patients with MSI-high colorectal
11 tumors," correct?
12 A I see that.
13 Q Why did you call out MSI-high colorectal
14 tumors in that sentence as opposed to MSI-low
15 colorectal tumors?
16 MS. BROWN-MARSHALL: Object to the form.
17 A So the point of this was we were discussing
18 the Hopkins trial that we were participating in.
19 Q Where do you mention the JHU study here?
20 A We don't, but that was why we made this
21 statement.
22 Q And it's your opinion that the JHU study

1 that you're referring to was intended to assess
2 MSI-high colorectal tumors?
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A If you read the hypothesis and the
6 protocol, it specifically states that it's an
7 experiment being done to assess the effect of PD-1
8 inhibitors in MSS colorectal cancer, MSI-high
9 colorectal cancer, and MSI-high non-colorectal
10 cancer.
11 Q Right. And you just mentioned MSS
12 colorectal cancer, whereas in your article at page 8
13 you don't mention MSS colorectal cancer, correct?
14 A That's correct. But I also don't mention
15 brain tumors or anal cancer or all kinds of things.
16 I mention what I mention. I don't mention what I
17 don't mention.
18 Q Are you saying that MSS colorectal cancer
19 has the same relevance to immunotherapy in colorectal
20 cancer as brain cancer?
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A The relevance of PD-1 inhibitors in a
2 variety of different cancers was not understood at
3 this time.
4 Q Was there intriguing data for the use of
5 anti-PD-1 agents in patients with MSS colorectal
6 tumors?
7 MS. BROWN-MARSHALL: Object --
8 A Well, the data that existed was the
9 Topalian study where one of 33 patients responded.
10 I'm not aware that they tested the microsatellite
11 instability status of the other 32 patients. But I
12 am aware that they tested one patient who responded,
13 as we discussed before the break, and that that
14 patient's tumor was MSI-high.
15 Q So you were not aware of any data that was
16 intriguing with respect to the use of anti-PD-1
17 agents for patients with MSS colorectal tumors,
18 correct?
19 A So I would say correct, but that was an
20 unresolved question that was tested in arm B of the
21 Hopkins trial.
22 Q But it's fair to say that the reason why

1 you specifically mentioned MSI-high colorectal tumors
2 in your article is that that is what the intriguing
3 data was related to. Yes?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A The intriguing data was related to the one
7 71-year old man from Detroit who responded to
8 nivolumab.
9 Q And you're referring to the patient who was
10 tested as MSI-high colorectal cancer, correct?
11 A I'm referring to the patient who responded
12 to nivolumab, who had colorectal cancer and whose
13 tumor turned out to be MSI-high.
14 MR. ZEILBERGER: Okay. Can the tech please
15 share, not on the screen, but share the file Exhibit
16 1117.
17 A So will that be put in the chat or on the
18 screen, on the Zoom screen?
19 Q It should be put into the chat location.
20 THE TECHNICIAN: And to clarify, counsel, I
21 do not believe I have access to 1117, unless it's
22 been provided in an alternate method.

1 Correction, I see it now. One moment,
2 please. It is uploading to the folder now.
3 A Okay. I have 1117 open in front of me.
4 Q And this is a document we have newly marked
5 as Exhibit 1117. It's not previously part of the
6 record.
7 Do you recognize this document,
8 Dr. Goldberg?
9 A I see that it says that it is the protocol
10 that we have been discussing that was published in
11 the Le paper and that it was referenced in the Le
12 paper.
13 Q And you have previously reviewed this
14 protocol, correct?
15 A Not recently.
16 Q When you prepared -- or when you were
17 involved in the preparation of the New England
18 Journal of Medicine article that you just referenced,
19 at that time you would have reviewed this protocol?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A So I reviewed this protocol when I was

1 participating in it, but that was almost a decade
2 ago.
3 Q Can you please turn to page 40 of 226 to
4 Exhibit 1117.
5 A Okay. It will take a minute to scroll
6 down. Okay. I have page 40 in front of me.
7 Q Page 40 is a study calendar, correct?
8 A Yes.
9 Q And there is a pre-study period of time,
10 correct?
11 A I see that.
12 Q And then following the pre-study period,
13 there is a 14-day cycle, correct?
14 A Correct.
15 Q And then following the 14-day cycle, there
16 is a 20-week period of time, correct?
17 A Correct.
18 Q And then following the 20 weeks it goes to
19 off study, correct?
20 A Correct.
21 Q Under the pre-study period of time, one of
22 the agenda items is informed consent, correct?

1 A Yes. So I'm noticing at the bottom of this
2 page that it says Original Version 1.1 May 30, 2013.
3 Is this the original version?
4 Q Are you asking, Dr. Goldberg, if this --
5 I'm not sure I understand your question,
6 Dr. Goldberg.
7 A Do you see at the bottom of the page under
8 "Tumor Biopsies," are you with me?
9 Q Yes, Dr. Goldberg.
10 A It says "Phase 2 Study of MK-3475 in
11 Patients with Microsatellite Unstable Tumors Original
12 Version 1.1 May 30, 2013." I didn't notice the date
13 of this document and I'm not sure if it's at the top.
14 I can go back and look.
15 Q Well, let's stick with this page for now,
16 Dr. Goldberg.
17 A Well, that's a critical question because
18 the protocol may have been amended and I don't know
19 whether this was the original version or a new
20 version.
21 Q I would like to understand how you
22 interpret this version of the protocol, Dr. Goldberg.

1 Under the pre-study period of time another agenda
2 item is inclusion/exclusion criteria, correct?
3 A Yes.
4 Q Another agenda item under pre-study is
5 demographics, correct?
6 A Can you refer me where in the protocol
7 you're looking? Are you still on page 40?
8 Q Yes.
9 A So I don't see -- I see inclusion/exclusion
10 criteria under pre-study, that's what you're
11 referring to?
12 Q And I just asked you about the next item,
13 demographics.
14 A Okay. I see that.
15 Q And under demographics is MSI testing,
16 correct?
17 A I see that.
18 Q And MSI testing is also part of the
19 pre-study period of time, correct?
20 A That's what it states here.
21 Q So assuming the protocol was conducted in
22 accordance with what is provided under the study

1 calendar at page 40 of Exhibit 1117, MSI testing
2 would have been conducted during the pre-study period
3 of time, correct?
4 MS. BROWN-MARSHALL: Object to the form of
5 the -- Dr. Goldberg, let me get my objection on the
6 record.
7 Object to the form of the question.
8 A So that's why I asked whether this was the
9 original version of the study or an amended version
10 of the study.
11 As you'll recall, at the time that Ohio
12 State activated the study, all patients who needed to
13 be accrued to the MSS arm of the trial had been
14 accrued. And so in order for a patient to be
15 eligible after that cohort had been filled, they
16 would have had to have MSI testing performed
17 pre-study, because if they were MSS, they were no
18 longer eligible. But my -- I'm unsure whether this
19 is the original version or a later version.
20 Q So if you turn to page 2, Dr. Goldberg,
21 that might help you. Or at least we can start there.
22 Page 2 indicates that this supplement, and this is a

1 supplement to the New England Journal of Medicine
2 article, contains the original protocol, the final
3 protocol, and the summary of changes, correct?
4 A I see that.
5 Q And if you turn to page 4 of 226, under
6 Protocol Type it indicates Original then Version 1,
7 May 1, 2013, and under that Original/Version 1.1 May
8 30th, 2013, correct?
9 A I see that.
10 Q Does that help you understand whether the
11 protocol that we are looking at is the original
12 version?
13 A I believe that that answers the question.
14 Thank you.
15 Q Turning back to page 40 of Exhibit 1117.
16 A Give me a minute to get there. Okay.
17 Q You would agree, then, that even in the
18 original version of the protocol, before you got
19 involved in the study, MSI testing was conducted
20 pre-study, correct?
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A So it specifies here that the testing
2 needed to be done, but it doesn't specify that the
3 results needed to be known.
4 Q Would it have been logical, Dr. Goldberg,
5 for a study protocol to specifically require MSI
6 testing to be pre-study and then not look at those
7 results pre-study?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So MSI testing is not a same day turnaround
11 study. MSI testing can be done several different
12 ways; one way is immunohistochemistry and another way
13 is PCR. Neither of those turn around quickly. They
14 end up oftentimes having to be sent to an outside lab
15 to be done, and so the reporting may be several days
16 or even weeks later than the ordering of the test.
17 Q Page 40 of the protocol Exhibit 1117
18 doesn't say that MSI testing was conducted same day,
19 correct?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A Can you point to what you're looking at on

1 that page? Or would you --
2 Q Let me ask it -- let me rephrase my
3 question.
4 The pre-study period of time is not a
5 single day, correct?
6 A The pre-study checklist, eligibility
7 checklist has to be filled out before a patient can
8 be enrolled in the study. But the studies do not
9 have to be conducted on the same day.
10 Q If we look at the visit windows, the very
11 first row, there's a 28-day period for the pre-study
12 window, correct?
13 A You're back on page 40?
14 Q I never left page 40, Dr. Goldberg.
15 A So I'm now back on page 40 and it says that
16 there's a 28-day period before enrollment during
17 which studies can be conducted, and that often is
18 done to accommodate imaging studies, which are
19 expensive and which you don't want to repeat unless
20 it's necessary.
21 Q And that also could have been done to
22 accommodate MSI testing, correct?

1 A It could, but not necessarily would.
2 Q Is it fair to say that you don't know one
3 way or the other whether that's how it was in fact
4 done in the 2013 MSI-high study?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A I don't see any data on this page that
8 tells me whether it was done before -- whether the
9 MSI testing results would have been available before
10 the patient was enrolled and treated.
11 Q And all I'm asking you, Dr. Goldberg, is to
12 confirm whether -- you don't know one way or the
13 other whether MSI testing was done for the 2013
14 MSI-high study during the pre-study period?
15 MS. BROWN-MARSHALL: Object to the form of
16 the question.
17 A So what I understand is that the MSI
18 testing had to have been ordered, but I don't know if
19 it was resulted before the patient was enrolled and
20 treated, according to what is stated here.
21 Q Okay. Let's turn back to your declaration,
22 paragraph 54.

1 A Okay. I'm on paragraph 54.
2 Q In the first sentence you say, "The finding
3 that PD-1 inhibitors had the potential to be an
4 active agent for a subset of patients with colorectal
5 cancer was unexpected," correct?
6 A It states that.
7 Q When you say that the discovery was
8 unexpected, that is from the perspective of the time
9 period before the MSI-high study record published,
10 correct?
11 MS. BROWN-MARSHALL: Object to the form of
12 the question.
13 A So my understanding is the MSI study record
14 the NCI. -- NCI ClinicalTrials.gov document?
15 Q No, Dr. Goldberg. I'm referring to the
16 2013 MSI-high study protocol that published as
17 Exhibit 1005 on June 10th -- or in June of 2013.
18 MS. BROWN-MARSHALL: Counsel, that was not
19 what you said in your original question. Please be
20 more consistent.
21 MR. ZEILBERGER: Counsel, Dr. Goldberg
22 asked me to clarify my question. Please don't

1 mischaracterize the record.
2 A So, again, I'm confused a little bit.
3 Please just ask me the question again so I can
4 reconsider it.
5 Q I can rephrase it.
6 When you say in paragraph 54 of your
7 declaration that the discovery was unexpected, that
8 is from the perspective of before June 2013 when the
9 2013 MSI-high study record published, correct?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A So the problem that I'm having is when the
13 MSI study record published. So at the time that we
14 enrolled in this trial, the trial was confidential,
15 it wasn't in the public domain. It was filed -- the
16 experimental plan was filed at NCI -- at
17 ClinicalTrials.gov, but the entire protocol was not
18 available there, at least I don't think it was.
19 Q Parts of the protocol were published on
20 ClinicalTrials.gov, correct?
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A I don't know that. Can you show it to me?
2 Q You were looking at it earlier,
3 Dr. Goldberg. It's Exhibit 1005, which you had
4 pulled up already earlier. If you want to refer to
5 it again, you're more than welcome to.
6 A Okay. I'm going to go back and refer to it
7 again just so that I'm sure I know what I'm talking
8 about. So I have it in front of me, it's a six-page
9 document, most of which is blank, and it has a study
10 description, which I previously read. This study
11 will be looking at whether pembro is effective in
12 three different patient populations. So that, as I
13 understand it, is what was published in this
14 document, not the clinical protocol.
15 Q Can you turn to paragraph 52 of your
16 declaration, please.
17 A Okay.
18 Q At the end of that paragraph you say that
19 [as read] "CRC is not associated with known mutagen
20 exposure and therefore those tumors would not likely
21 have the high mutational burden and high level of
22 mutation associated with neoantigens that predict

1 that PD-1 inhibitors will work in melanoma and small
2 cell lung cancers," correct?
3 A I see that.
4 Q Is MSI-high colorectal cancer associated
5 with high mutational burden?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A MSI-high colorectal cancer is a small
9 subset, as we've established, in colorectal cancers,
10 and MSS colorectal cancers are not MSI-high. And in
11 either circumstance, mutagen exposure is not
12 understood to be applicable to carcinogenesis in the
13 colon.
14 Q Do I need to repeat my question,
15 Dr. Goldberg? I don't believe you answered it.
16 A Please repeat it.
17 Q Is MSI-high colorectal cancer associated
18 with high mutational burden?
19 MS. BROWN-MARSHALL: Objection; asked and
20 answered.
21 A MSI-high colorectal cancer is not
22 associated with mutagen exposure, but it is

1 associated with a high level of neoantigens.
2 Q Did I ask you about mutagen exposure?
3 MS. BROWN-MARSHALL: Objection;
4 argumentative.
5 A That's in the sentence that you're
6 referencing.
7 Q And when I asked you is MSI-high colorectal
8 cancer associated with high mutational burden, you
9 answered that it's not associated with mutagen
10 exposure, but it is associated with a high level of
11 neoantigens.
12 Are you agreeing or disagreeing that
13 MSI-high colorectal cancer is associated with high
14 mutational burden?
15 MS. BROWN-MARSHALL: Objection; asked and
16 answered.
17 A So I guess I should say please refer to my
18 prior answer, which is a part of the record.
19 Q I would like an answer to my question,
20 Dr. Goldberg.
21 MS. BROWN-MARSHALL: Objection; asked and
22 answered.

1 A Please refer to my prior answer to the same
2 question.
3 Q What is that answer, Dr. Goldberg?
4 MS. BROWN-MARSHALL: Objection; asked and
5 answered.
6 A Can the reporter read it back to us?
7 Q I have the text of your answer,
8 Dr. Goldberg. That's not the issue.
9 You're refusing to say whether or not
10 MSI-high cancer is associated with high mutational
11 burden. Are you able to answer that with a yes or
12 no?
13 MS. BROWN-MARSHALL: Objection; asked and
14 answered.
15 A So the problem that I'm having is that you
16 referred me to paragraph 52 of my report, which has a
17 sentence that has an "and" in it, and the mutagen
18 exposure is relevant to the statement that I made
19 about the fact that CRC would be a less interesting
20 target for ongoing study of the PD-1 inhibitor.
21 So if you would like me to answer the
22 question outside of the context of that statement in

1 my declaration, I will tell you that, yes, MSI-high
2 colorectal cancers have a high mutational burden.
3 Q Is it your opinion that before the alleged
4 priority dates of the '393 patent, it was not known
5 that MSI-high colorectal cancer was associated with
6 high mutational burden?
7 MS. BROWN-MARSHALL: Object to the form of
8 the question.
9 A No.
10 Q Are you saying no, that's not your opinion,
11 or no, it was not known?
12 A Please restate your question.
13 Q Is it your opinion that before the alleged
14 priority dates of the '393 patent, it was not known
15 that MSI-high colorectal cancer was associated with
16 high mutational burden?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A It is my opinion that it was known that
20 high mutational load was associated with MSI-high
21 colon cancer. I don't know why you put a "not" in
22 your sentence other than possibly to confuse me.

1 Q Keytruda was approved for advanced melanoma
2 before the alleged priority date of the '393 patent,
3 correct?
4 A Yes.
5 Q Even by 2010, word began to filter through
6 to Merck that nivolumab was showing signs of promise,
7 correct?
8 MS. BROWN-MARSHALL: Objection; outside the
9 scope of the declaration.
10 A I've had no contact with Merck so I have no
11 idea what they knew.
12 Q And you didn't review any documents that
13 dealt with what Merck knew in 2010?
14 MS. BROWN-MARSHALL: Object to the form of
15 the question.
16 A I reviewed the Topalian paper, which
17 recounted the nivo study that she and the Hopkins
18 team did for -- in collaboration with BMS. I did not
19 review any Merck documents or reports of Merck's
20 knowledge or lack of knowledge of mechanisms of
21 action.
22 Q Did you review any documents that discussed

1 Merck's knowledge of mechanisms of action?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A The introduction to the Topalian study
5 discusses the mechanisms of action of PD-1
6 inhibitors, and I reviewed that paper.
7 Q Were you aware that in 2010 Merck
8 reactivated IND development for pembrolizumab?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A I was not aware of that. I was not aware
12 that they had inactivated IND development.
13 MR. ZEILBERGER: Can the tech please share
14 as a file Exhibit 2051.
15 THE TECHNICIAN: Please stand by. The file
16 is uploading now.
17 A Please repeat the name of the file.
18 Q It's Exhibit 2051.
19 A It hasn't yet uploaded for me.
20 THE TECHNICIAN: If you refresh your page,
21 Doctor, does it appear now?
22 THE WITNESS: 2051. Okay. Yes, I see it.

1 A That's the Forbes article.
2 Q This is the Forbes article that you
3 mentioned earlier, correct?
4 A Correct.
5 Q And it's an article that you cite in your
6 declaration, correct?
7 A Correct.
8 Q And you reviewed this article and relied on
9 it for your declaration?
10 A I did review this article.
11 Q And you relied on it for your declaration?
12 A I don't remember when I reviewed it,
13 whether it was before the declaration or later.
14 Q Can you please turn to page 7 of Exhibit
15 2051.
16 A Okay. I'm on page 7.
17 Q And in the first full paragraph the Forbes
18 article indicates that everything changed, however,
19 by the middle of 2010, correct?
20 A I see that sentence.
21 Q And towards the bottom of that same
22 paragraph, it says that "word began to filter through

1 to Merck that nivolumab, or nivo (brand name:
2 OPDIVO), an earlier-stage molecule targeting PD-1
3 that BMS also acquired," it says "though" but I think
4 it should say "through its recent acquisition of
5 Medarex, was showing signs of promise," correct?
6 A I see that.
7 Q Before I just brought this to your
8 attention, you were not aware of this information.
9 Is that right?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A So I read this article, but I read many
13 articles in preparation for this, and I did not
14 remember every sentence of every article that I read.
15 Q And in the next paragraph of Exhibit 2051,
16 "From what was literally a standing stop, Merck
17 urgently reactivated IND development in mid-2010,
18 targeting a filing by the end of the year and
19 achieving it in December," correct?
20 A I see that.
21 Q When you prepared your declaration, were
22 you aware that in 2010 Merck had reactivated IND

1 development of Keytruda?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A So I remember reading this paragraph, and
5 part of the reason I remember that is Eric Rubin was
6 the oncologist who took care of my mother when she
7 had ovarian cancer, but I didn't remember the details
8 of the IND development by Merck.
9 Q And if we look towards the bottom of page
10 7, the Forbes article indicates that "The results
11 from the melanoma cohort were striking," and that's
12 referring to Merck's melanoma cohort, correct?
13 MS. BROWN-MARSHALL: Objection;
14 mischaracterizes the document.
15 A I see the sentence that "The results from
16 the melanoma cohort were striking."
17 Q So you disagree that that relates to a
18 Keytruda melanoma cohort?
19 MS. BROWN-MARSHALL: Objection to the form
20 of the question.
21 A I can't tell what it refers to. In the
22 next sentence it refers to a pembro study and the

1 quote from Dr. Ribas.
2 Q I see. So it's your understanding that
3 Keytruda and pembro are two different things?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A Let me just read. I'm going to start in
7 the paragraph above to try and get better context
8 here.
9 Okay. Now I understand this better, having
10 read the paragraph above. So ask me your question
11 again, please.
12 Q The melanoma cohort that is referenced as
13 having striking results at the bottom of page 7
14 relates to a Keytruda cohort, correct?
15 A Correct.
16 Q And Keytruda is the brand name for
17 pembrolizumab, correct?
18 A Correct.
19 Q And if you go on to page 9 of Exhibit 2051.
20 A Okay. I'm on page 9.
21 Q The Forbes article indicates that "Merck
22 scientists involved in the program tell me they

1 needed little prodding from Ribas, saying they were
2 acutely aware of both the potential clinical utility
3 of their drug and the commercial need to close the
4 gap with a competitor who seemed to be years ahead."
5 Do you see that?
6 A Yes. Let me just read it again.
7 Okay. I see that sentence.
8 Q Do you have an opinion on whether -- well,
9 strike that.
10 Do you agree or disagree with the statement
11 in the Forbes article that the Merck scientists were
12 acutely aware of both the potential clinical utility
13 of their drug and the commercial need to close the
14 gap with a competitor who seemed to be years ahead?
15 MS. BROWN-MARSHALL: Objection; outside the
16 scope of the declaration.
17 A So I neither disagree or agree with the
18 statement that Mr. Shaywitz made. I accept that he
19 fact checked his statements before he made them.
20 Q Can you turn back to your declaration,
21 please.
22 A Okay. What paragraph?

1 Q Can you turn to paragraph 58.
2 A Okay. I have that in front of me.
3 Q You note in paragraph 58 how Keytruda
4 obtained breakthrough therapy designation for the
5 treatment of patients with MSI-high colorectal
6 cancer, correct?
7 A I see that sentence, yes.
8 Q You don't mention how Keytruda had received
9 an earlier breakthrough therapy designation for
10 advanced melanoma, correct?
11 A My report focuses on colorectal cancer.
12 Q So it's your opinion that the earlier
13 breakthrough therapy designation for Keytruda for
14 advanced melanoma was not relevant?
15 MS. BROWN-MARSHALL: Objection --
16 A Not relevant to what?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A Was not relevant to what?
20 Q To the use of Keytruda for MSI-high
21 colorectal cancer.
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A So if you look at the keynote series of
3 studies that Merck has done, their first success was
4 in melanoma, and then they ran clinical trials in at
5 least a dozen other tumor types. So the relevance to
6 doing those studies was they saw a good result in one
7 of kind of tumor and they wanted to run experiments
8 to see if that good result could be replicated in
9 other tumors.
10 They didn't make the assumption, nor would
11 the FDA allow them to, that success in one kind of
12 cancer treatment would be translatable to other types
13 of cancer treatments without running a trial.
14 Q What document were you referencing,
15 Dr. Goldberg, in providing that answer?
16 MS. BROWN-MARSHALL: Objection. Object to
17 the form of the question.
18 A I was referencing my experience as an
19 expert witness, not a document.
20 Q I can see you're looking at a document,
21 Dr. Goldberg, so I would just like to know what
22 you're looking at. I can't see it. Your screen

1 blurs it.
2 A My declaration. It is the only document
3 that I have in front of me. You asked me to look at
4 paragraph 52 in the document, so I was following your
5 orders.
6 Q Would you agree that nivolumab was the
7 first PD-1 inhibitor that was developed?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A I don't know the answer to that. I know it
11 was the first PD-1 inhibitor to get an FDA approval,
12 but I'm not sure -- there are many PD-1 inhibitors
13 and I'm not sure of the timeline of their
14 development.
15 Q I see. So if you go up to paragraph 50 of
16 your declaration, would you amend your first sentence
17 to refer to FDA approval?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A I think it would be reasonable to amend it
21 because the rest of the paragraph talks about the
22 clinical trial that led to the evidence that the FDA

1 considered in approving the study. Laboratory
2 development and clinical development are two
3 different things, and I was referring to clinical
4 development.
5 Q If you go down to paragraph 53.
6 A Okay.
7 Q Four lines from the bottom you refer to a
8 patient's -- the sensitivity of a patient's tumor to
9 pembrolizumab. Do you see that?
10 A Let me read the sentence.
11 I see that.
12 Q Would you agree that's a mistake?
13 A No.
14 Q So which responding CRC patient are you
15 referring to in paragraph 53?
16 A The 71-year old man treated on the Topalian
17 study, that was the one patient out of 33 patients
18 treated with nivo who responded to nivolumab and who
19 had subsequent MSI testing done to show that that
20 patient was MSI-high.
21 Q Are you saying that nivolumab and
22 pembrolizumab are the same thing?

1 MS. BROWN-MARSHALL: Objection;
2 mischaracterizes previous testimony.
3 A Of course not.
4 Q So what did you mean when you refer to
5 sensitivity of that patient's tumor to pembrolizumab?
6 A So that actually is a misstatement. It
7 should have been nivolumab.
8 Q Is there a reason why when I asked you
9 earlier if it was a mistake, you said no?
10 MS. BROWN-MARSHALL: Objection; argumentative.
11 A I did not read the full sentence.
12 Q When -- strike that.
13 Do you have an understanding as to why the
14 JHU scientists did not want to conduct their study
15 using nivolumab?
16 MS. BROWN-MARSHALL: Objection. Object to
17 the form of the question.
18 A So as I understand it from what I have been
19 told by the JHU scientists, they first approached BMS
20 with their study proposals to test a PD-1 inhibitor
21 in MSI-high colon cancer and BMS declined to support
22 the study.

1 So they then went to Merck and made the
2 same pitch and had the same response; Merck declined
3 to support the study. But Merck eventually agreed to
4 provide the drug without additional monies to support
5 the study at the time the study was initiated.
6 Q What is your understanding as to why the
7 JHU scientists went to BMS first to try to use
8 nivolumab?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A So I think you'll have an opportunity to
12 depose the JHU scientists and you can ask them
13 directly.
14 My supposition is that the one patient who
15 had responded had been treated with nivo, so they
16 wanted to test that in a larger sample of patients.
17 Q What is your understanding as to why the
18 JHU scientists went to Merck second to try to use
19 pembrolizumab?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A For the same reason I just stated. There

1 was a response in that one 71-year old man to
2 nivolumab, and they wanted to extend the experience
3 of treatment with a PD-1 inhibitor in MSI-high colon
4 cancer, it would make sense to extend the experience
5 in a circumstance where a patient had already been
6 treated with that drug and shown a response.
7 Q But why would the JHU scientists have
8 specifically picked pembrolizumab as their second
9 choice as opposed to a different PD-1 inhibitor?
10 MS. BROWN-MARSHALL: Object to the form of
11 the question.
12 A You're going to have to ask the JHU
13 scientists that question.
14 Q Is that because you don't know the answer
15 to the question?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A I can speculate, but I wasn't a part of the
19 discussions or the solicitations of the drug
20 companies for support.
21 Q What would be your speculation?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A My speculation is that they really wanted
3 to test the hypothesis that PD-1 inhibitors would
4 work in MSI-high patients. And when they couldn't
5 get support from BMS, they looked for another source
6 of a PD-1 inhibitor and therefore went to Merck.
7 Q Is it fair to say that the prior
8 breakthrough therapy designation for pembrolizumab
9 would have played a factor in whether the JHU
10 scientists wanted to use pembrolizumab for their
11 study?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A You keep asking me what the JHU scientists
15 were thinking. I did not participate in these
16 deliberations, nor was I a part of their
17 solicitations for support or for access to drug.
18 Q Would the prior breakthrough therapy
19 designation for pembrolizumab have played a factor
20 for a person of ordinary skill in the art in deciding
21 which PD-1 inhibitor to use for the study?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A No.
3 Q So you're testifying that, all else being
4 equal, a person of ordinary skill in the art would
5 have considered a PD-1 inhibitor that has no prior
6 approvals on equal footing with a PD-1 inhibitor that
7 has prior approvals?
8 MS. BROWN-MARSHALL: Objection;
9 mischaracterizes previous testimony.
10 A I didn't say that.
11 Q Can you please explain your answer of "no"
12 then?
13 MS. BROWN-MARSHALL: Object to the form of
14 the --
15 (Simultaneous speaking.)
16 MS. BROWN-MARSHALL: Dr. Goldberg, let me
17 get my objection.
18 Object to the form of the question.
19 A Nivolumab had prior FDA approval and
20 pembrolizumab had prior FDA approval, so both were
21 drugs that had a record of benefit in other tumor
22 types and both should be considered for testing of a

1 new hypothesis, such as the ability of a PD-1
2 inhibitor to be of benefit to patients with MSI-high
3 tumors.
4 Q You understand, Dr. Goldberg, that there
5 were other PD-1 inhibitors in existence before the
6 2013 MSI-high study started that had no prior
7 approvals. Yes?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So I don't have specific knowledge of what
11 PD-1 inhibitors besides pembro and nivo were under
12 development, but I suspect that there were multiple
13 PD-1 inhibitors under development based upon the
14 subsequent studies that have occurred after that
15 time.
16 Q And the fact that pembrolizumab was one of
17 the PD-1 inhibitors that had received an approval for
18 an indication would have played a factor in deciding
19 which PD-1 inhibitor to use for the study, correct?
20 MS. BROWN-MARSHALL: Object to the form of
21 the question.
22 A Again, you keep asking me to tell you what

1 the Hopkins team thought, and I was not a part of
2 their deliberations.
3 Q I'm not asking you what the Hopkins team
4 thought, Dr. Goldberg.
5 I'm asking what a person of ordinary skill
6 in the field would have thought at that time, whether
7 they would have factored this.
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So a person of ordinary skill in the art,
11 who wanted to test the hypothesis that a PD-1
12 inhibitor would be beneficial to patients with
13 microsatellite instability high tumors, would look at
14 the universe of PD-1 inhibitors, would look at their
15 progress and development and the clinical experience
16 with them, and would likely pick the agent or agents
17 for which there was the most experience because they
18 would be well-characterized with regard to toxicity
19 and tolerability.
20 Q Now, you say in your declaration that both
21 BMS and Merck were not willing to fund the study,
22 correct?

1 MS. BROWN-MARSHALL: Object to the form of
2 the question.
3 A I say that on the basis of communications
4 with the Hopkins team and having read the Forbes
5 article.
6 Q What is your understanding, then, on why
7 the study was ultimately performed using
8 pembrolizumab and not nivolumab?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A So my understanding is that BMS was
12 unwilling to provide their drug and Merck was willing
13 to provide their drug.
14 Q Do you have an understanding as to why
15 Merck was willing to provide their drug?
16 MS. BROWN-MARSHALL: Object to the form of
17 the question.
18 A I never had any direct conversations with
19 Merck about pembrolizumab.
20 Q Do you have an understanding from anyone as
21 to why Merck was willing to provide their drug?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A So I had conversations with the Hopkins
3 team and I read the Forbes article.
4 Q Do you have an understanding from your
5 conversations with what you call the Hopkins team or
6 the Forbes article as to why Merck was willing to
7 provide their drug?
8 A I don't understand -- I don't have an
9 opinion as to why they were. I only have an opinion
10 or I can only recognize the fact that they did
11 provide it.
12 Q Can you go back to paragraph 49 of your
13 declaration, and please let me know when you're
14 there.
15 A Okay.
16 Q In the last sentence of paragraph 49 you
17 say, "Prior to JHU's clinical trial that demonstrated
18 that PD-1 inhibitors were effective in treating
19 MSI-high/dMMR solid tumors, PD-1 inhibitors had
20 failed to be effective in treating CRC cancers,"
21 correct?
22 A That's what it states.

1 Q The nivolumab study that successfully
2 treated one patient with MSI-high colorectal cancer
3 occurred prior to JHU's clinical trial that you
4 reference in paragraph 49, correct?
5 A That's correct.
6 MS. BROWN-MARSHALL: Counsel, we have been
7 going for over an hour. Would now be a good time to
8 take at a break?
9 MR. ZEILBERGER: I think it's been just
10 about an hour.
11 Q But, Dr. Goldberg, did you want to take a
12 break?
13 A You know, this is a long process, and I
14 think an hourly break is a reasonable thing to do on
15 a regular basis.
16 Q No problem. I just wanted to make sure you
17 wanted a break. Happy to take a break. You just
18 need to let me know.
19 A Okay.
20 MR. ZEILBERGER: Let's go off the record.
21 (Recess 2:06 p.m. - 2:17 p.m.)
22 BY MR. ZEILBERGER:

1 Q Dr. Goldberg, can you please go to
2 paragraph 61 of your declaration.
3 A Okay.
4 Q In paragraph 61, in the second sentence you
5 say, "While pembrolizumab is a PD-1 inhibitor like
6 nivolumab had been tested in a group of patients with
7 MSS tumors, it is a different drug." Do you see
8 that?
9 A Yes. So there's a -- the word "that"
10 should be present in that sentence between
11 "nivolumab" and "had been."
12 Q So you're saying in the sentence that both
13 pembrolizumab and nivolumab had been tested in a
14 group of patients with MSS tumors. Is that right?
15 MS. BROWN-MARSHALL: Object -- object to
16 the form of the question.
17 Q Can you please explain what you meant in
18 this sentence?
19 A Nivolumab is a PD-1 inhibitor that had been
20 tested in a group of patients with MSS tumors. While
21 pembrolizumab is also a PD-1 inhibitor, it is a
22 different drug.

1 Q Why do you say that nivolumab had been
2 tested in a group of patients with MSS tumors?
3 MS. BROWN-MARSHALL: Object to the form of
4 the -- object to the form of the question.
5 A So it had been tested in the Topalian study
6 in 33 patients with colorectal cancer. We don't know
7 the microsatellite stability status of all of those
8 patients, but you would predict at least 85 percent
9 of them would have been MSS.
10 Q Isn't it true that the only status of a
11 patient in the Topalian study that you do know is
12 MSI-high?
13 MS. BROWN-MARSHALL: Object to the form of
14 the question.
15 A So the only patient whose microsatellite
16 instability tumor status that I know of is that of
17 the 71-year old man. I don't know if Topalian and
18 colleagues had MSI testing results on other patients.
19 And so what I am stating is that since 85
20 percent or more of patients with colorectal cancer
21 are MSS, regardless of whether they had been tested,
22 the majority of the patients enrolled in the Topalian

1 study would have been MSS based on statistics.
2 Q In paragraph 61 you don't say a majority of
3 the patients would have had MSS tumors, correct?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A I'm saying that now. I didn't say it in
7 there.
8 Q You agree -- would you agree that the
9 Topalian study that you referred to showed that
10 nivolumab is not effective in treating MSS colorectal
11 cancer?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A So since I don't know the MS -- the
15 microsatellite status of the patients in the Topalian
16 study, I can't say specifically.
17 But as I stated just a moment ago, the vast
18 majority of those patients with colorectal cancer who
19 are unselected with regard to microsatellite
20 instability status would have likely been MSS, and
21 only one of 33 responded.
22 Q A person of ordinary skill in the art

1 reading the Topalian study would have thought that
2 nivolumab is not effective for treating MSS
3 colorectal cancer, correct?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A So, again, there was no data presented on
7 the microsatellite status of the tumors in the
8 patients who were enrolled in the Topalian study. So
9 I'm not sure that a POSA would make any conclusion
10 with respect to differentiating MSI-high from MSS
11 patients for that cohort.
12 Q Dr. Goldberg, you differentiated in
13 paragraph 61 where you said nivolumab had been tested
14 in a group of patients with MSS tumors, did you not?
15 MS. BROWN-MARSHALL: Objection; asked and
16 answered.
17 A So I'll go through it again. 85 percent of
18 patients with colon cancer at least are MSS. This
19 was a group of 33 patients. The high likelihood is
20 about 25 percent of them or more -- or 25 of those 33
21 or more would have been MSS.
22 So, indeed, nivolumab was tested in a

1 cohort of patients who were MSS, but I'm not certain
2 of the individual patients' MSS status.
3 Q I wasn't asking you if you're certain about
4 the individual patients' MSS status.
5 I asked you whether a person of ordinary
6 skill in the art reading the Topalian study would
7 have thought that nivolumab is not effective for
8 treating MSS colorectal cancer.
9 A I believe that they would have concluded
10 that, yes, based on the logic that I've provided
11 repeatedly and in my status as a POSA.
12 Q In paragraph 61 you go on to say that "it
13 was important to independently test pembrolizumab's
14 potential for benefit in mCRC patients with MSS
15 tumors," correct?
16 A Yes.
17 Excuse me just a minute. The lights just
18 went out on me. I think I'm going to move my seat
19 because I think the sensor doesn't know that I'm at
20 the end of the table.
21 Q No problem.
22 A I'm situated now. Can you ask me the

1 question again, please.
2 Q There's no question pending yet. I had
3 asked you about the sentence in paragraph 61 where
4 you say that "it was important to independently test
5 pembrolizumab's potential for benefit in mCRC
6 patients with MSS tumors." Do you remember me
7 pointing you to that?
8 A Yes, I see that sentence.
9 Q Was there anything about pembrolizumab that
10 was known at the time that would have suggested it
11 would be effective for MSS tumors where nivolumab was
12 not effective?
13 MS. BROWN-MARSHALL: Object to the form of
14 the question.
15 A So we're talking about two drugs. They are
16 drugs that are in the same class. They're both PD-1
17 inhibitors. But when we have multiple drugs in a
18 drug class, we don't make any assumptions about
19 whether because one is active or inactive, the other
20 is going to be inactive or active. The test has to
21 be done with that drug in that population.
22 Q I'm not asking you about assumptions,

1 Dr. Goldberg. I'm asking you whether there was
2 anything about pembrolizumab that was known at the
3 time that would have suggested it would be effective
4 for MSS tumors where nivolumab was not effective?
5 MS. BROWN-MARSHALL: Objection; asked and
6 answered.
7 A So I can't really state the universe of
8 knowledge about pembrolizumab, much of which was
9 proprietary at that time. So I believe the drug
10 needed to be tested, so did the Hopkins investigator
11 team and the IRBs that determined the ethical
12 considerations with regard to entering patients on a
13 trial of pembrolizumab in MSS patients did not object
14 to it because the efficacy was unknown at that time.
15 Q Under what theory was it thought that
16 pembrolizumab may be effective for treating MSS
17 colorectal cancer?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A I don't really know how to answer that.
21 Pembrolizumab hadn't been tested in this setting, and
22 therefore the only way to know whether it was

1 effective or not was to conduct the experiment.
2 Q You would agree I, assume, Dr. Goldberg,
3 that drugs are not given at random in the hopes that
4 they treat a random illness?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A Again, you put "nots" in there and it makes
8 it hard to understand the question that you're
9 asking. Could you ask it as an affirmative question
10 rather than as a negative question, please?
11 Q Clinical trials are conducted to test a
12 hypothesis, correct?
13 A Correct.
14 Q Under what hypothesis would pembrolizumab
15 have been effective in treating MSS colorectal
16 cancer?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A Pembrolizumab had not been tested in MSS
20 colon cancer. Therefore, one could hypothesize that
21 it could be effective, and the only way to know that
22 for sure would be to treat some patients with it and

1 see if it was effective.
2 Q On what basis could one hypothesize that
3 pembrolizumab could be effective in treating MSS
4 colorectal cancer?
5 MS. BROWN-MARSHALL: Objection; asked and
6 answered.
7 A Because it had not previously been tested
8 in that setting.
9 Q Besides the fact that pembrolizumab had not
10 previously been tested in the treatment of MSS
11 colorectal cancer, is there any basis whatsoever to
12 think that it would have been effective in treating
13 MSS colorectal cancer?
14 MS. BROWN-MARSHALL: Object to the form of
15 the question.
16 A So I can answer that from the perspective
17 of today when we know that there are some patients
18 with MSS colorectal cancer that respond to
19 pembrolizumab.
20 In fact, there were several in Dr. Le's
21 study that had tumor shrinkage who were MSS if you
22 look at the curves from her New England Journal

1 Article, the swimmer plots from her New England
2 Journal article.
3 We also know that other measures of tumor
4 mutational burden, such as TMV, that are different
5 than MSI-high testing, can predict more responses to
6 PD-1 inhibitors in some circumstances. I don't
7 believe that that was really well-understood in 2013,
8 but it is understood now.
9 Q Besides the fact that pembrolizumab had not
10 previously been tested in the treatment of MSS
11 colorectal cancer, in 2013, what is your
12 understanding as to the basis to think that
13 pembrolizumab could have been effective in treating
14 MSS colorectal cancer?
15 MS. BROWN-MARSHALL: Objection; asked and
16 answered.
17 A I believe this is the fourth or fifth time
18 you've asked me that question and I feel like I've
19 answered it to the best of my ability. If you keep
20 asking me the same question, I will give you the same
21 answer, that I've already answered it to the best of
22 my ability.

1 Q Dr. Goldberg, in the previous answer you
2 gave me you specifically said, well, I don't know
3 about 2013, but thinking about today.
4 The most recent question is about 2013. I
5 know your counsel said asked and answered, which
6 might have led you to give me the response you gave
7 me, but I would like your answer.
8 MS. BROWN-MARSHALL: Is there a question
9 pending?
10 MR. ZEILBERGER: There is, counsel.
11 A Can you ask the question, please?
12 Q Besides the fact that pembrolizumab had not
13 previously been tested in the treatment of MSS
14 colorectal cancer, in 2013, what is your
15 understanding as to the basis to think that
16 pembrolizumab could have been effective in treating
17 MSS colorectal cancer?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A So unless a drug is specifically tested in
21 a specific patient population, one cannot say whether
22 it would be effective or would not be effective

1 without doing the study.
2 Q Turning to paragraph 60 of your
3 declaration.
4 A Okay.
5 Q In the paragraph -- in the sentence
6 bridging pages 39 and 40, you say, "Had the results
7 of the trial been obvious before it was conducted,
8 i.e. that it was obvious that the MSS cohort would
9 not respond, it would have been unethical to
10 construct such a protocol, let alone enroll patients
11 to cohort B, and IRB would not have approved the
12 trial," correct?
13 A I see the sentence as you read it.
14 Q What do you mean by "obvious" in that
15 sentence?
16 A If there was no hope that there could be
17 any benefit for a specific patient subgroup, it would
18 be unethical to treat that subgroup with that
19 particular intervention.
20 I'm going to get up because the lights in
21 here are still flashing, I'm going to see if I can
22 stop them --

1 Q No problem.
2 A Okay. I think I may have fixed it.
3 Q It would have been ethical to include the
4 MSS cohort in the 2013 MSI-high study even if there
5 was optimism that the MSI-high cohorts would respond
6 well, correct?
7 MS. BROWN-MARSHALL: Object to the form of
8 the question.
9 A The two cohorts are separate, and I don't
10 see how it's relevant that how one cohort would
11 respond would determine whether it was ethical to
12 treat another cohort in a basket trial such as this.
13 Q So you agree that even if there was
14 optimism about the MSI-high cohorts before the 2013
15 MSI-high study was conducted, that would not have
16 made it unethical to include the MSS cohort, correct?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A So 85 percent of patients with metastatic
20 colorectal cancer are MSS and those patients die of
21 colon cancer. So experiments to try and improve
22 their outcomes was an unmet need and remains an unmet

1 need.
2 Q In the sentence you were just talking
3 about, is it fair to say that you characterized the
4 results of the trial as the MSS cohort not
5 responding?
6 MS. BROWN-MARSHALL: Object to the form of
7 the question.
8 A I don't understand the question. Could you
9 please restate it?
10 Q In the sentence bridging pages 39 and to 40
11 of your declaration, you say, "Had the results of the
12 trial been obvious before it was conducted, i.e. that
13 it was obvious that the MSS cohort would not
14 respond." Do you see that?
15 A I see that.
16 Q So you're describing in that sentence as
17 one of the results of the trial, that the MSS cohort
18 did not respond, fair?
19 A That the MSS cohort would not respond. The
20 study hadn't been done yet, so nobody knew if they
21 would respond or not.
22 Q Was one of the results of the 2013 MSI-high

1 study that the MSS cohort did not respond?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A Well, if you look at the figures in the New
5 England Journal of paper article, there were some
6 patients who were MSS who had tumor shrinkage, but
7 whose response was not sufficient to meet the NCI's
8 definition of a partial response. You could argue
9 that those patients had some benefit from the
10 treatment even though they didn't meet the definition
11 of a partial response. And actually, their duration
12 of response was apparently prolonged -- their
13 progression-free survival, to be more precise, was
14 apparently prolonged in some circumstances in some
15 individuals.
16 Q Separate from the MSS cohort, another one
17 of the results of the trial was that the MSI-high
18 cohorts did respond, correct?
19 MS. BROWN-MARSHALL: Object to the form of
20 the question.
21 A So not every patient whose tumor was
22 MSI-high did respond. But some patients whose tumors

1 were MSI-high showed evidence of a response.
2 Q Are you disputing whether the MSI-high
3 cohorts of the 2013 MSI-high study were successful?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A Of course not. The fact that not every
7 patient benefits doesn't take away from the fact that
8 the patients who benefited got a positive result from
9 it.
10 Q Okay. I didn't ask you whether every
11 patient benefited, Dr. Goldberg.
12 If it was obvious before the MSI study was
13 conducted that patients in the MSI-high cohorts would
14 respond well to pembrolizumab, would you agree that
15 that would not make it unethical to include an MSS
16 cohort?
17 MS. BROWN-MARSHALL: Object to the form of
18 the question.
19 A Another one of these convoluted questions
20 with a "not" thrown in in the middle. Please try to
21 restate your question in a way that --
22 Q Let's take it in parts, Dr. Goldberg.

1 First part. This is the premise. I want
2 you to assume that before the 2013 MSI-high study,
3 that it was obvious, before the 2013 MSI-high study
4 was conducted, that patients in the MSI-high cohorts
5 would respond well to pembrolizumab.
6 Are you with me?
7 A Well, I understand what you're saying, but
8 why would I assume that? That hadn't been tested.
9 Q I'm asking you to assume it.
10 A Okay.
11 Q Are you able to assume it for purposes of
12 this question --
13 A It is an incorrect assumption on the basis
14 of history, but we'll pretend that that was the case.
15 Q With that assumption, even if that
16 assumption was true, that would not make it unethical
17 to include the MSS cohorts, correct?
18 MS. BROWN-MARSHALL: Object to the form of
19 the question.
20 A I don't think it's relevant. There are two
21 different cohorts of patients and the hypothesis
22 needed to be tested in both cohorts. You don't in

1 oncology say, well, this works in one cohort of
2 patients, so we're not going to test it in another
3 cohort of patients who might benefit until you test
4 it to see if they do.
5 Q But you agree with me that it would not be
6 unethical to have the MSS cohort in that situation,
7 correct?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So I'm going to say I believe it would have
11 been ethical today or back in 2013 to enroll patients
12 with MSS colorectal cancer in this trial.
13 Q And it would have been ethical to enroll
14 patients with MSS colorectal cancer in this trial in
15 2013 even if it was obvious that patients with MSS --
16 MSI-high -- excuse me. Let me start over.
17 It would have been ethical to enroll
18 patients with MSS colorectal cancer in this trial in
19 2013 even if it was obvious that patients with
20 MSI-high colorectal cancer would respond well,
21 correct?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A I would say asked and answered. You have
3 asked me this question four or five times. I assume
4 you're hoping that I'll give you a different
5 response, but I'm not going to.
6 It was ethical to enroll MSS patients even
7 if the science would have suggested that MSI-high
8 patients had a higher likelihood of response.
9 Q Can you please turn to paragraph 47 of your
10 declaration.
11 A Okay.
12 Q Sorry, one moment.
13 In paragraph 47 you refer to "a new era in
14 immune system-based cancer treatment," correct?
15 MS. BROWN-MARSHALL: Objection;
16 mischaracterizes the document.
17 A I'll read you the sentence. "Their
18 discovery and clinical development ushered in a new
19 era in immune system-based cancer treatment."
20 Q Did I misread one of the words there,
21 Dr. Goldberg?
22 A I read the words.

1 Q And you also refer to immuno-oncology
2 agents, correct?
3 A Correct.
4 Q And this paragraph is under a section
5 header labeled "No Effective Immuno-Oncology
6 Treatments for CRC Prior to JHU's clinical trial,"
7 correct?
8 A That's -- yes, that's correct. It's item C
9 in bold on page 30.
10 Q Are you saying that the long-felt need
11 addressed by the '393 patent was a need for
12 immuno-oncology agents for colorectal cancer?
13 MS. BROWN-MARSHALL: Object to the form of
14 the question.
15 A Can you repeat the question, please?
16 Q Are you saying that the long-felt need
17 addressed by the '393 patent was a need for
18 immuno-oncology agents for colorectal cancer?
19 MS. BROWN-MARSHALL: Same objection.
20 A So yes, the '393 patent was a development
21 that affected a subset of patients with colorectal
22 cancer, but did not address the unfelt need for the

1 85 percent of patients who were not MSI-high or the
2 approximately 50 percent of patients who are MSI-high
3 who have no response to PD-1 inhibitors.
4 Q If you can turn back to paragraph 27.
5 A Okay.
6 Q In paragraph 27 you say, "In my opinion,
7 Keytruda (pembrolizumab) and its microsatellite
8 instability-high related FDA-approved indications,
9 which embody the inventions claimed in the '393
10 patent, fulfilled a long-felt, but previously unmet
11 need for an effective treatment for MSI-high
12 colorectal cancer, with the most pressing need being
13 treatments for metastatic colorectal cancer,"
14 correct?
15 A I see that sentence, yes.
16 Q So are you testifying that the long-felt
17 need addressed by the '393 patent was a need for an
18 effective treatment for MSI-high colorectal cancer?
19 A Please repeat the question.
20 Q Are you testifying that the long-felt need
21 addressed by the '393 patent was a need for an
22 effective treatment for MSI-high colorectal cancer?

1 A Yes.
2 Q When did the need for an effective
3 treatment for MSI-high colorectal cancer materialize?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A So there's been a need for treatment for
7 MSI-high colorectal cancer since colorectal cancer
8 was diagnosed. So I would assume it probably
9 happened a millennia ago.
10 Q MSI-high colorectal cancer was diagnosed a
11 millennia ago?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A People had MSI-high colorectal cancer then;
15 we just didn't know what it was. MSI-high, the
16 microsatellite instability was discovered in the late
17 20th century.
18 Q For how long -- strike that.
19 Since when was it known that there could be
20 a specific treatment for MSI-high colorectal cancer?
21 MS. BROWN-MARSHALL: Object to the form of
22 the question.

1 A That was discovered in 2015 with the
2 publication of the Le paper.
3 Q So are you saying that the Le paper
4 addressed a need that people didn't know existed?
5 MS. BROWN-MARSHALL: Object to the form of
6 the question.
7 A The short answer is no. That seems like a
8 silly question.
9 Q So for how long did people know there was a
10 need for a specific treatment for MSI-high colorectal
11 cancer?
12 MS. BROWN-MARSHALL: Object to the form of
13 the question.
14 A Since MSI-high colorectal cancer was
15 discovered, there has been a need to treat it. And
16 it was -- so Lynch syndrome was first suspected by
17 Henry Lynch, for whom the syndrome is named, who is a
18 clinical oncologist with genetics training, working
19 at Creighton University in Omaha.
20 He took care of patients with large
21 families, many of whom had multiple family members
22 who died of colon cancer or endometrial cancer. He,

1 therefore, hypothesized that colorectal cancer could
2 be the result of an inherited cancer susceptibility
3 syndrome. He was not a laboratory scientist, so he
4 did not elucidate the underpinnings of that from a
5 molecular genetics perspective.
6 Later, laboratory investigators such as
7 Albert de la Chapelle, who I mentioned earlier, who
8 was at Ohio State, Bert Vogelstein at Johns Hopkins,
9 and some investigators from Sweden elucidated the
10 biologic abnormality of mismatch repair defect that
11 is the causative genetic abnormality that results in
12 Lynch syndrome and in some microsatellite high
13 colorectal cancers.
14 Other patients with colorectal cancer, did
15 not have an inherited genetic susceptibility, they
16 acquire their mismatch repair defect for unknown
17 reasons, probably some interplay between heredity,
18 environment and exposures.
19 Q Still in paragraph 27, where you say "with
20 the most pressing need being treatments for
21 metastatic colorectal cancer," are you saying that
22 the '393 patent addressed a long-felt need for

1 metastatic colorectal cancer?
2 MS. BROWN-MARSHALL: Object to the form of
3 the question.
4 A So could we turn to the '393 patent that's
5 cited later in my report so that I can refer to that?
6 I'll look for it and see if I can find it.
7 On page 47 number -- paragraph number 74.
8 Are you there?
9 Q Go ahead.
10 A So if you'll note in this claim 1 of the
11 '393 patent, it makes no reference to the stage of
12 colorectal cancer for which this invention is
13 patented. It just states, "A method of treating
14 microsatellite instability high or DNA mismatch
15 repair deficient colorectal cancer in a human
16 patient." It doesn't state whether that human
17 patient has stage 1, 2, 3 or 4 colorectal cancer.
18 Q Are you correcting the testimony you have
19 in paragraph 27 where you say that the '393 patent
20 fulfilled a long-felt, but previously unmet need for
21 an effective treatment for MSI-high colorectal cancer
22 with the most pressing need being treatments for

1 metastatic colorectal cancer?
2 MS. BROWN-MARSHALL: Objection;
3 mischaracterizes previous testimony.
4 A I stand by that statement.
5 Q So you are saying that the '393 patent
6 fulfilled a long-felt need directed to metastatic
7 colorectal cancer?
8 MS. BROWN-MARSHALL: Objection.
9 A You're misrepresenting the sentence. Let
10 me read the sentence to you.
11 "In my opinion, Keytruda and its
12 microsatellite instability-high related FDA-approved
13 indications, which embody the inventions claimed in
14 the '393 patent, fulfilled a long-felt, but
15 previously unmet need for effective treatment of
16 MSI-high colorectal cancer."
17 Like the patent, I don't specify a stage in
18 making that statement. But I add that the most
19 pressing need was for metastatic colorectal cancer.
20 So from my interpretation of this sentence,
21 it includes all patients with colorectal cancer, but
22 it calls out those with metastatic colorectal cancer,

1 who virtually always die of their disease, as having
2 the most pressing need.
3 Q I asked you whether you're saying the '393
4 patent fulfilled a long-felt need directed to
5 metastatic colorectal cancer and you said I'm
6 misrepresenting you.
7 So do you disagree with the statement that
8 the '393 patent fulfilled a long-felt need directed
9 to metastatic colorectal cancer?
10 MS. BROWN-MARSHALL: Objection; asked and
11 answered.
12 A The '393 patent fulfilled a long-felt need
13 for treatment of metastatic colorectal cancer.
14 Q Is it your opinion that it fulfilled a
15 long-felt need for treatment of MSS metastatic
16 colorectal cancer?
17 A If you read the FDA indication, it only
18 includes patients with MSI-high colorectal cancer.
19 Q I'm asking you about the '393 patent,
20 Dr. Goldberg.
21 A The '393 patent doesn't make any statement
22 about MSS colorectal cancer, that I recall.

1 Q So when you refer to metastatic colorectal
2 cancer in paragraph 27, are you referring to MSI-high
3 metastatic colorectal cancer?
4 A I am.
5 Q You say in paragraph 27 that "Keytruda and
6 its microsatellite instability-high related FDA-
7 approved indications embody the inventions claimed in
8 the '393 patent," correct?
9 A Right.
10 Q What is that opinion based on?
11 A Let me read the sentence again.
12 So can you ask the question again? I'm not
13 quite sure what you're asking.
14 Q In paragraph 27 you say that "Keytruda and
15 its microsatellite instability-high related
16 FDA-approved indications embody the inventions
17 claimed in the '393 patent." Is that correct?
18 A That's correct.
19 Q What is that opinion based on?
20 A It's based on the claim 1 of the patent.
21 Q What analysis did you do to compare claim 1
22 of the patent to Keytruda and its MSI-high related

1 FDA-approved indications?
2 A My declaration.
3 Q Can you please explain what you mean?
4 A I put together a 52-page report addressing
5 that question.
6 Q You have 52 pages in your report directed
7 to the issue of whether Keytruda and its MSI-high
8 related FDA-approved indications are embodied in the
9 inventions claimed in the '393 patent?
10 A I believe that that's what this declaration
11 focuses on, yes.
12 Q Can you please turn to paragraph 51 of your
13 declaration.
14 A Okay.
15 Q You observe in paragraph 51 that Merck
16 conducted its own studies using pembrolizumab in
17 melanoma in non-small cell lung cancer, correct?
18 A Correct.
19 Q And those studies by Merck were partially
20 in response to BMS's experience with nivolumab,
21 correct?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A So that is a logical conclusion, but I am
3 not in touch with representatives from Merck to know
4 exactly what their logic was.
5 Q Did you not believe this statement to be
6 true when you included it in your declaration,
7 Dr. Goldberg?
8 MS. BROWN-MARSHALL: Objection; argumentative.
9 A Of course I believed it to be true or I
10 would not have put it in my declaration.
11 Q You go on to say in paragraph 51 that "The
12 Merck studies in patients with melanoma and non-small
13 cell lung cancer showed similar activity as that
14 observed with nivolumab in these diseases," correct?
15 A Yes. That's references by Robert and by
16 Reck that are noted at the bottom of the page.
17 Q Would a person of ordinary skill in the art
18 have been surprised to see that pembrolizumab showed
19 similar activity as nivolumab for patients with
20 melanoma and non-small cell lung cancer?
21 A I believe they would not have been
22 surprised, but they wouldn't have known whether that

1 was the case unless the experiment had been done.
2 Q They would not have been surprised because
3 they have similar mechanisms of action, correct?
4 A Correct. But the FDA would not have
5 approved pembrolizumab on the basis of BMS's
6 experience without appropriate trials.
7 MR. ZEILBERGER: I think we have been going
8 for about a break -- about an hour. Would you like a
9 break?
10 THE WITNESS: Sure. We'll reconvene at
11 3:15?
12 MR. ZEILBERGER: Why don't we do 3:20.
13 (Recess 3:09 p.m. - 3:21 p.m.)
14 BY MR. ZEILBERGER:
15 Q Dr. Goldberg, after the results from the
16 nivolumab study published in 2013, is it fair to say
17 that the development of treatments using PD-1
18 inhibitors for MSI-high cancer progressed rapidly?
19 MS. BROWN-MARSHALL: Object to the form of
20 the question.
21 A As compared to what?
22 Q As compared to typical progress for cancer

1 treatment.
2 A So I would say --
3 MS. BROWN-MARSHALL: Object to the form of
4 the question.
5 A It's fair to say that there was a great
6 amount of interest, as was stated in the paper that
7 Kristen Ciombor and I wrote and that we discussed
8 earlier --
9 (Court Reporter clarification.)
10 A As we discussed earlier in the paper by
11 Dr. Ciombor and I, there was intense interest on the
12 part of clinical oncologists, on the part of
13 patients, and on the part of pharmaceutical companies
14 of testing PD-1 inhibitors as quickly as possible to
15 be sure that patients with cancer could realize their
16 potential benefit.
17 Q Is it fair to say, then, that a person of
18 ordinary skill in the art would have been optimistic
19 enough about the MSI-high cohorts in the 2013
20 MSI-high study to want to obtain the data from that
21 study?
22 MS. BROWN-MARSHALL: Object to the form of

1 the question.
2 A So I think we all wanted to know how well
3 these worked and wanted to see studies done and to
4 get the results of the studies as quickly as
5 possible.
6 Q That is because there was some optimism
7 about how these drugs would work, correct?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So as I said before, response rates in
11 melanoma and non-small cell lung cancer patients, who
12 had been previously treated in the double digits, was
13 unprecedented and very exciting.
14 Q Before the break we were talking about the
15 claimed invention. Do you remember that?
16 A I do. Can you refer me to a paragraph on
17 the report, please?
18 Q Paragraph 27, where I guess you say in the
19 opposite way, inventions claimed in the '393 patent.
20 A Okay.
21 Q When we talked about that before, you
22 pointed me to claim 1 of the '393 patent, correct?

1 A Correct.
2 Q Is claim 1 of the '393 patent the only
3 claim that you assessed for your declaration?
4 MS. BROWN-MARSHALL: Object to the form of
5 the question.
6 A I read and assessed the entire '393 patent.
7 Q Can you please show me where you analyze
8 any claims other than claim 1 of the '393 patent?
9 MS. BROWN-MARSHALL: Object to the form of
10 the question.
11 A So from my perspective, claim 1 of the '393
12 patent is an umbrella claim, and the other claims of
13 the patent are subsidiary to that umbrella claim. So
14 I felt that by addressing claim 1, I was addressing
15 the other claims within the patent.
16 Q In paragraph 71 of your declaration. Are
17 you there?
18 A Yes.
19 Q In paragraph 71 of your declaration you say
20 that "Prior to the May 2017 approval of the MSI-high
21 indication, Keytruda was not approved for any
22 indications that allowed for the treatment of

1 colorectal cancer patients. Practically, this meant
2 that doctors would not prescribe Keytruda to CRC
3 patients outside of the context of a clinical trial,"
4 correct?
5 A Correct.
6 Q So that it is your opinion that prior to
7 May 2017, there would not have been any sales of
8 Keytruda for the treatment of MSI-high colorectal
9 cancer, correct?
10 MS. BROWN-MARSHALL: Objection;
11 mischaracterizes the document.
12 A So as I understand it, Keytruda was on the
13 market for the non-small cell and bladder and
14 Hodgkin's disease and melanoma indications, and so a
15 clinical oncologist could write a prescription for
16 it.
17 Having said that, it was a very expensive
18 drug and most patients couldn't afford to pay for it
19 out of pocket.
20 As noted at the bottom of page 45, Merck
21 may have had a compassionate use protocol. I don't
22 know whether they did or not. But if they did, they

1 would have had to provide the agent free of charge to
2 patients because they didn't have an FDA-approved
3 indication.
4 Q Do you have an opinion as to whether there
5 would have been any sales of Keytruda for the
6 treatment of MSI-high colorectal cancer prior to May
7 2017?
8 MS. BROWN-MARSHALL: Object to the form of
9 the question.
10 A So you represent Merck, you probably could
11 ask them. I don't have specific knowledge of whether
12 there were any sales or not.
13 Q Now, I understand you spoke to Mr. Segers
14 about this proceeding, correct?
15 A He's the economic expert? Is that correct?
16 Q JHU holds him out as such, yes.
17 A I did have a conversation with him.
18 Q Did you provide any opinions to Mr. Segers?
19 A So that conversation was with two lawyers
20 from Fish, and I don't know whether it's privileged.
21 Can someone advise me about that?
22 MS. BROWN-MARSHALL: It's okay to answer

1 these questions. I'll caution you if you get close
2 to privileged information.
3 A Okay. Mr. Segers did most of the talking.
4 I mostly listened to what he had to say.
5 Q What did he have to say to you?
6 A He talked about the economic success of
7 Keytruda sales and how that was a sign that it met
8 one of the eight indicia that we specified earlier in
9 this report.
10 Q And in what fashion did that impact your
11 analysis in your declaration?
12 A I didn't address the economic success of
13 this drug. I was asked to address the unmet need.
14 Q Are you saying, then, that the conversation
15 you had with Mr. Segers was not relevant to your
16 opinions?
17 MS. BROWN-MARSHALL: Objection;
18 mischaracterizes previous testimony.
19 A My conversation with him was relevant to my
20 understanding of the issues involved in this patent,
21 but is not cited or referenced in my declaration.
22 Q Did you provide Mr. Segers with an

1 understanding about how or whether the claims of the
2 '393 patent correspond with the use of pembrolizumab
3 for its MSI-high indications?
4 A I do not have a memory of giving him any
5 such information, no.
6 Q What information did you provide Mr. Segers?
7 A As I mentioned, I mostly listened to what
8 he had to say.
9 Q I recall that, and I suppose I'm latching
10 onto the word "mostly." Was there any information
11 you provided Mr. Segers?
12 A I think we had some small talk. But I
13 don't believe that I provided him any substantive
14 information contained in my report. He was
15 interested in telling me what he was opining on, not
16 listening to what I was opining on, and that wasn't
17 the purpose of the call.
18 Q And was it just a single call that you had
19 with him? Or did you have any other conversations
20 with him?
21 A I had a single call with him.
22 Q Going down to paragraph 73 of your

1 declaration.
2 A Okay.
3 Q In paragraph 73 you say, "An oncologist
4 reviewing the Keytruda label would understand that a
5 CRC patient treated under either of these indications
6 would be treated in response to determining that that
7 patient's tumor is either MSI-high or dMMR by testing
8 the patient's tumor," correct?
9 A I see that statement.
10 Q What do you mean by "in response to" in
11 that statement?
12 MS. BROWN-MARSHALL: Objection; calls for a
13 legal conclusion.
14 A So the sense of this sentence is that an
15 oncologist or a POSA reviewing the label would
16 understand that they needed to do MSI testing to
17 determine if the patient was likely to benefit or
18 meet the indications for treatment with
19 pembrolizumab.
20 Q So are you saying, then, that there would
21 not need to be an MSI-high determination?
22 A I'm saying that there would need to be an

1 MSI-high determination.
2 Q In paragraph 77 of your declaration, if you
3 could move forward a little bit.
4 A Okay.
5 Q You say in paragraph 77 that "there is a
6 nexus between the claims of the '393 patent and the
7 methods of treating MSI-high CRC according to the
8 Keytruda label," correct?
9 A I see that sentence, yes.
10 Q When you use the word "nexus" there, what
11 do you mean?
12 A Essentially, a connection.
13 Q What do you mean by "connection"?
14 A That the patent covers the invention of a
15 method for treating patients with MSI-high colorectal
16 cancer with pembrolizumab and I would say based on
17 all of the information that we've exhaustively
18 reviewed today.
19 MR. ZEILBERGER: Okay. Let's take a
20 five-minute break.
21 MS. BROWN-MARSHALL: Okay.
22 (Recess 3:40 p.m. - 3:49 p.m.)

1 BY MR. ZEILBERGER:
2 Q Dr. Goldberg, have you ever developed a
3 clinical trial on a novel cancer therapy?
4 A Yes.
5 MS. BROWN-MARSHALL: Objection; vague.
6 Q Which novel cancer therapy did you -- for
7 which did you develop a clinical trial?
8 A There are multiple clinical trials that
9 when I was at Mayo Clinic and University of North
10 Carolina and Ohio State we had phase 1 programs that
11 were testing first-in-man drugs, as well as
12 first-in-man combinations, and I can't remember all
13 the names of them. I don't have my CV in front of
14 me, but I could pull it up and look at it, if that
15 would be of use.
16 Q You said that -- you referred to "we" at
17 your time at Mayo Clinic and the University of North
18 Carolina, Ohio State. Did you personally develop
19 those clinical trials involving novel cancer
20 therapies?
21 A So we worked in teams and we rotated the
22 responsibility of being the principal investigator on

1 clinical trials, but we participated in each others'
2 trials and we participated in the monitoring of each
3 others' trials.
4 Q Did you write the protocol for any of the
5 trials you're referring to that involved novel cancer
6 therapy?
7 A So I wrote a number of trials, yes.
8 Q Which therapies were they directed to?
9 A Well, let me pull up my CV so I can refresh
10 my memory. This has been quite awhile ago. Is that
11 all right?
12 Q That's fine.
13 A It's going to take me a minute.
14 MS. BROWN-MARSHALL: Maybe it would be
15 easier, counsel, do you have his CV? It should be
16 attached to his declaration. Do you have that as an
17 exhibit?
18 MR. ZEILBERGER: Counsel, I believe you
19 made it part of his exhibit. Did you not provide
20 Dr. Goldberg with his full declaration today?
21 MS. BROWN-MARSHALL: So, Dr. Goldberg, do
22 you have a physical copy of your CV with your

1 declaration, or do you just have the declaration
2 itself?
3 THE WITNESS: I just have the declaration
4 itself. But I have my CV up in a Word document. I
5 just need to get to the relevant places on it. It
6 will just take me a minute.
7 A Okay. So one of the studies that I had
8 looked at was a drug called Octreotide, or
9 somatostatin, in the treatment of patients with
10 asymptomatic advanced colorectal cancer. This was
11 done in 1995.
12 Let's see. I wrote a trial with a drug
13 called fazarabine. Ara-AC is another name for it.
14 This was in 1997.
15 Developed a phase 1 study of duocarmycin in
16 patients with refractory cancers in 1998.
17 Do you want me to keep going?
18 Q Let's pause for a second. The drugs that
19 you just listed, which I believe are somatostatin,
20 fazarabine, and duocarmycin -- well, I guess, first,
21 did I get those right?
22 A More or less, enough so that it's not worth

1 fussing with the names.
2 So somatostatin ended up being an approved
3 drug. The other two were failures and were never --
4 never went beyond early phase testing.
5 Q With respect to somatostatin, was the trial
6 that you conducted, did that lead to the approval of
7 somatostatin?
8 A It did not --
9 MS. BROWN-MARSHALL: Object. Object to the
10 form of the question.
11 A Somatostatin was not ever approved for
12 treatment of colorectal cancer. It was approved for
13 treatment of carcinoid tumors and neuroendocrine
14 tumors, based on other studies that we did at Mayo
15 Clinic, but not ones I was the principal investigator
16 for.
17 Q Dr. Goldberg, during any of the breaks
18 during today's deposition did you speak to anyone or
19 receive any information whatsoever regarding this
20 proceeding?
21 A I received no information. I spoke to
22 Casey because we were in the same room and she was

1 leaving and so we had a social conversation, but it
2 had nothing to do with proceedings that we have going
3 on.
4 I did email a former patient during one of
5 the breaks, but it had nothing to do with this.
6 MR. ZEILBERGER: Thank you very much for
7 your time today, Dr. Goldberg. We have no further
8 questions.
9 MS. BROWN-MARSHALL: Thank you, counsel.
10 EXAMINATION
11 BY MS. BROWN-MARSHALL:
12 Q Dr. Goldberg, I have just a couple
13 questions for you.
14 Do you remember counsel asking you
15 questions regarding the 2013 MSI-high clinical trial?
16 A I do. There were quite a lot of questions
17 about that.
18 Q Okay. And what is your understanding of
19 what the 2013 MSI-high clinical trial is?
20 A I believe that they were discussing the
21 trial that we participated in run by Dr. Le and
22 reported in the New England Journal in 2015.

1 Q Okay. And is that the clinical trial
2 that's identified as NCT01876511?
3 MR. ZEILBERGER: Objection; leading.
4 A Give me a minute and I can give you the
5 number. I believe it's -- that would be specified, I
6 believe, in the ClinicalTrials.gov, which I guess I
7 can pull up because it's in the folder. Is that
8 correct?
9 Q Counsel -- sorry, Dr. Goldberg, I'm not
10 sure what you're referring to. Let me re-ask my
11 question.
12 A Okay.
13 MR. ZEILBERGER: I do want to make clear
14 that the exhibits are still available. I think you
15 might be referring to Exhibit 1005, Dr. Goldberg, and
16 it should still be there for you.
17 A Okay. Let me just pull it up and I'll
18 verify the number of -- the NCI.gov number of the
19 trial.
20 So it's NCT01876511.
21 Q Okay. And looking at Exhibit 1005, do you
22 see that there's a section called "Study Record

1 Versions"?
2 MR. ZEILBERGER: Objection; leading.
3 A I see a notation in the ClinicalTrials.gov
4 archive where about halfway down the page it says
5 "Study Record Versions," yes.
6 Q Okay. And what was the date of the first
7 study record version for the clinical trial with
8 NCT01876511?
9 A It states June 10th, 2013.
10 Q Okay. And what is the date of the last
11 entry for the study record version for NCT01876511?
12 A The final one, number 28, was posted on
13 February 4th, 2020 and is stated to be study status.
14 MS. BROWN-MARSHALL: Okay. No further
15 questions.
16 THE WITNESS: Does that mean that we are
17 concluded?
18 MS. BROWN-MARSHALL: Counsel can decide if
19 they're going to ask any follow-up questions, so
20 we're waiting for them.
21 MR. ZEILBERGER: Just take a quick
22 two-minute break, if you don't mind.

1 MS. BROWN-MARSHALL: That's fine.
2 (Recess 4:01 p.m. - 4:04 p.m.)
3 MR. ZEILBERGER: Thank you again,
4 Dr. Goldberg. We have no additional questions.
5 THE WITNESS: Okay. Thank you, everyone.
6 (Time noted: 4:05 p.m.)
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1 CERTIFICATE OF CERTIFIED SHORTHAND REPORTER
2 NOTARY PUBLIC
3 I, MONIQUE VOUTHOURIS, Certified Court Reporter
4 and Notary Public within and for the State of New
5 Jersey, do hereby certify:
6 That RICHARD M. GOLDBERG, M.D., the witness
7 whose remote deposition is hereinbefore set forth,
8 was duly sworn by me before the commencement of such
9 deposition, and that such deposition was taken
10 before me and is a true record of the testimony
11 given by such witness.
12 I further certify that the adverse party, THE
13 JOHNS HOPKINS UNIVERSITY, was represented by counsel
14 at the deposition.
15 I further certify that the deposition of
16 RICHARD M. GOLDBERG, M.D., occurred remotely via
17 Zoom Videoconference, on Friday, December 13, 2024,
18 commencing at 9:05 a.m. EST to 4:05 p.m. EST.
19 I further certify that I am not related to any
20 of the parties to this action by blood or marriage,
21 I am not employed by or an attorney to any of the
22 parties to this action, and that I am in no way

1 interested, financially or otherwise, in the outcome
2 of this matter.
3
4 IN WITNESS WHEREOF, I have hereunto set my hand
5 this 18th day of December 2024.
6
7
8
9 _____
10 Monique Vouthouris, CCR, RPR, CRR
11 Notary Public of the State of New Jersey
12 My commission expires: April 8, 2029
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